Their
IN THE COURT OF COMMON PLEAS
STARK COUNTY, OHIO

STARK COUNTY, OHIO BOARD OF COUNTY COMMISSIONERS
110 Central Plaza South, Suite 240,
Canton, Ohio 44702

And

THE CITY OF CANTON,
151 Lincoln Way East
Massillon, Ohio 44646

And

THE CITY OF MASSILLON,
Two James Duncan Plaza
Massillon, OH 44646

And

THE CITY OF ALLIANCE,
504 East Main Street,
Alliance, Ohio 44601

And

THE STATE OF OHIO *EX REL.* PROSECUTING ATTORNEY OF STARK COUNTY, JOHN D. FERRERO, 110 Central Plaza South, Suite 510, Canton, Ohio 44702; DIRECTOR OF LAW OF CITY OF CANTON, KRISTEN BATES AYLWARD, 218 Cleveland Avenue S.W., 7th Floor, Canton, Ohio 44702; DIRECTOR OF LAW OF CITY OF MASSILLON, ANDREA SCASSA, Two James Duncan Plaza, Massillon, OH 44646; and DIRECTOR OF LAW OF CITY OF ALLIANCE, JENNIFER L. ARNOLD, 470 E. Market St., Alliance, OH 44601

Case Number: 2018-CV-02230

Judge: Chryssa N. Hartnett

1:18 OP 46340

Amended Complaint

(Jury Demand Endorsed Hereon)

Plaintiffs,

vs.

PURDUE PHARMA L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

And

PURDUE PHARMA, INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

And

THE PURDUE FREDERICK
COMPANY INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

And RHODES PHARMACEUTICALS
L.P.
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

TEVA PHARMACEUTICALS USA,
INC.
c/o Corporate Creations Network Inc.
119 East Court Street
Cincinnati, OH 45202

And

CEPHALON, INC.
1090 Horsham Road
North Wales, PA 19454

And

JOHNSON & JOHNSON

c/o Terri Johnson
10219 Salineville Road NE
Salineville, OH 43945

And

JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.
c/o CT Corporation System
4400 Easton Commons
Suite 125
Columbus, OH 43219

And

ENDO HEALTH SOLUTIONS INC.
1400 Atwater Drive
Malvern, PA 19355

And

ENDO PHARMACEUTICALS, INC.
c/o CT Corporation System
4400 Easton Commons
Suite 125
Columbus, OH 43219

And

MALLINCKRODT, LLC
c/o CT Corporation System
4400 Easton Commons Suite 125
Columbus, OH 43219-6230

And

MALLINCKRODT, PLC
675 McDonnell Blvd.
St. Louis, MO 63042

And

SPECGX LLC
3600 North Second Street
Saint Louis, MO 63147

And

INSYS THERAPEUTICS
133 S Spectrum Blvd #100
Chandler, AZ 85286

And

JANE DOES 1 – 50

Defendants.

PRELIMINARY STATEMENT

1. Plaintiffs County of Stark, Ohio, by and through the Stark County Prosecutor's Office (the "County"), the City of Canton, the City of Massillon, and the City of Alliance (collectively "Plaintiffs") bring this action to redress Purdue Pharma, L.P.'s, Purdue Pharma, Inc.'s, the Purdue Frederick Company Inc.'s, Teva Pharmaceuticals USA's, Cephalon, Inc.'s, Janssen Pharmaceuticals, Inc.'s, Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s, Janssen Pharmaceutica Inc.'s, Endo Health Solutions Inc.'s, and Endo Pharmaceuticals Inc.'s, Insys Therapeutic, Inc.'s, Mallinckrodt, plc's, and Mallinckrodt LLC's (collectively, "Defendants") campaign of unfairly, deceptively, and fraudulently marketing and promoting opioids.

2. Defendants Purdue Pharma, L.P., Purdue Pharma Inc., and the Purdue Frederick Company Inc. (collectively "Purdue"), Teva Pharmaceuticals USA, Inc. and Cephalon, Inc. (collectively, "Teva"), Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica Inc. (collectively "Janssen"), Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. (collectively "Endo"), Insys Therapeutics, Inc. ("Insys") and Mallinckrodt, LLC, Mallinckrodt plc, and SpecGx LLC ("collectively "Mallinckrodt") manufacture, market, and sell prescription opioid pain medications, including the brand-name drugs OxyContin, Butrans, Hysingla ER, Actiq, Fentora, Opana/Opana ER, Percodan, Percocet, Zydone, Nucynta/Nucynta ER, Duragesic, Exalgo, and Xartemis XR.

3. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, and they are regulated as controlled substances. While opioids can dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience withdrawal symptoms—including severe anxiety, nausea, headaches, tremors, delirium, and pain—which are often

prolonged, if opioid use is delayed or discontinued. When using opioids continuously, patients grow tolerant to their analgesic effects (i.e. to relief of pain)—requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

4. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain—where brief use limited the need for escalating doses and the risk of addiction—or for palliative (end-of-life) care.[1] Consequently, the market for prescription opioids was sharply constrained.

5. To expand their market and profits, Defendants initiated, and for years have maintained, a deceptive marketing scheme that was intentionally designed to, and effectively did, change the perception of opioids to permit and encourage the use of opioids long-term for widespread chronic conditions like back pain, migraines, and arthritis. Beginning in the mid-1990s Purdue, later joined by the other Defendants began to promote opioids generally, and their own opioids in particular, as safe, effective, and appropriate for even long-term use for routine pain conditions.

6. To convince doctors and patients that opioids can and should be used to treat chronic pain, Defendants had to convince them that long-term opioid use is both safe, by minimizing and understating the risks, especially the serious risk of addiction, and helpful, by overstating the benefits.

7. Defendants used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and misleading statements about the risks and benefits of long-term opioid use. In this way, they tainted the sources that doctors and patients

[1] In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

relied upon for guidance, including treatment guidelines, continuing medical education programs, medical conferences and seminars, and scientific articles.

8. As part of this strategy, Defendants misrepresented the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use.

9. Specifically:

a. Defendants told doctors that patients receiving opioid prescriptions—even patients taking opioids long-term for chronic pain—generally would not become addicted, and that doctors could use screening tools to exclude patients who might.

b. Defendants told doctors that patients who did appear addicted were not; they were instead "pseudoaddicted" and should be given more opioids.

c. Defendants told doctors that opioids relieved pain when used long-term, without any studies to support this claim and without disclosing the lack of evidence that opioids were safe or effective long-term or the other risks from long-term use of opioids.

d. Defendants told doctors that opioids could be taken in higher and higher doses without disclosing the increased risk to patients.

e. Purdue told doctors that OxyContin provided 12 hours of relief when Purdue knew that, for many patients, it did not.

f. Defendants promised that opioids would improve patients' function and quality of life while trivializing or omitting the many adverse effects of opioids that diminish patients' function and quality of life.

g. Faced with a rising tide of opioid addiction, overdose, and death—precisely the risks that they denied in their marketing—Purdue and Endo falsely promoted their abuse-deterrent opioids as preventing abuse and "safe." But the "abuse-deterrent" features of their opioids could be easily defeated and did not limit oral abuse (the most common form of abuse).

h. Purdue also misrepresented its efforts to rein in the diversion and abuse of opioids, while privately failing to report suspicious prescribing.

10. Defendants' scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often

first-line, treatment. Defendants' deceptive marketing scheme also increased the comfort level of doctors and patients in converting opioids prescribed for acute pain—surgery or injuries, for example—to long-term use by patients who experienced or reported ongoing pain.

11. Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the Centers for Disease Control and Prevention ("CDC"), opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain.

12. Stark County is no exception to this trend, but has encountered prescription rates exceeding this already unfortunately high baseline. Each year from 2007 to 2015, the County had a prescription rate of more than 100% -- equating to more than one prescription for every man, woman, and child in the County. The prescription rate remained shockingly high — 92.6 opioid prescriptions for every 100 people (including children) in the County — in 2016.

13. As a direct and foreseeable result of Defendants' conduct, the nation and Stark County are now swept up in what the CDC has called a "public health epidemic" and what the U.S. Surgeon General has deemed an "urgent health crisis."[2] In 2015, an estimated 2 million Americans were addicted to prescription opioids and 591,000 to heroin. From 1999 to 2016, more than 200,000 people died in the U.S. from overdoses related to prescription opioids—more than the number of Americans who died in the Vietnam War.

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[2] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), available at http://www.cdc.gov/washington/testimony/2014/t20140429.htm;. Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at http://turnthetiderx.org.

14. The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose, and death; black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids.

15. Thus, rather than compassionately helping patients, this explosion in opioid use—and Defendants' profits—has come at the expense of chronic pain patients. According to the director of the CDC, one out of every 550 patients started on opioid therapy die of opioid-related causes a median of 2.6 years after their first opioid prescription.[3] As the then CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[4]

16. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care settings struggles with addiction. Prescription opioids at the molecular level and in their effect, closely resemble heroin. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain. And, the link between prescription narcotic painkiller abuse and subsequent and/or simultaneous heroin abuse continues to grow. Across the country, **80% of recent heroin users** have previously used prescription opioids non-medically. As the American Society of Addiction Medicine has explained, four out of five people who try heroin today started with prescription painkillers. In fact, people who are addicted to prescription opioids are 40 times more likely to

[3] Frieden and Houry, Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline, NEJM, 4/21/16, at 1503.

[4] *Id.*

become addicted to heroin, and the Centers for Disease Control and Prevention ("CDC") identified addiction to prescription opioids as the strongest risk factor for heroin addiction.

17. This transition became even more dangerous in recent years, as increasingly powerful synthetic opiates began entering communities. Heroin may be combined with fentanyl—a powerful opioid prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into Ohio communities, including Stark County.

18. In 2016, the CDC reported that, in contrast to other developed countries, and despite having some of the world's highest spending on medical care, our nation saw life expectancy at birth decline for the second straight year, with the increasing number of people who died of overdoses representing the most significant factor in this alarming trend.

19. Not only has the opioid epidemic been described as the deadliest drug crisis in American history, drug overdoses rose to become the leading cause of death for Americans under 50 years old, eclipsing guns or car accidents or accidents. Overdoses have been killing people at a pace faster than the H.I.V. epidemic did at its peak. According to Robert Anderson, who oversees death statistics at the CDC, "'I don't think we've ever seen anything like this. Certainly not in modern times.'"[5]

20. Ohio is among the states hardest hit by the opioid epidemic. As a recent report from The Ohio State University summarizes, "[o]pioid addiction, abuse, and overdose deaths have

[5] Associated Press, *Drug Overdoses Killed 50,000 in U.S., More than Car Crashes*, (Dec. 9, 2016), https://www.nbcnews.com/health/health-news/drug-overdoses-killed-50-000-u-s-more-car-crashes-n694001

become the most pressing public health issue facing Ohio."[6] The rapid rise in overdose deaths in Ohio and the United States as a whole is unprecedented. In 2017, reporting revealed that Ohio now "leads the country in drug overdose deaths per capita, a rate that continues to rise, overwhelming families, communities, and local governments across the state."[7] Overdose deaths have become the leading cause of death for Ohioans under the age of 55, and across all ages, more than two and half times as many people die from drug overdoses as from car accidents. Most of the overdose fatalities in Ohio involved opioids.

21. Once again, Stark County is no exception to this deadly trend. Since the beginning of 2012, more than 400 lives in the County have been cut short by prescription opioids. During the same time frame, 286 people died of overdoses linked to illicit opiates, to which people who have become addicted to prescription opioids often transition.

22. The loss of each of these individuals cannot be adequately conveyed by statistics, nor can the depth and breadth of the impact on those who survive. Because the addictive pull of opioids is so strong, relapse is more common than with other drugs. Hundreds of people have been rushed to local emergency rooms or revived by EMS or community members trained to administer Narcan — an antidote to overdose. In the first five months of 2018 alone, County emergency rooms treated 275 drug overdoses. The epidemic does not discriminate, but has effected every part of the community.

23. The damage inflicted cuts across ages and generations. Children are being displaced from their homes and raised by relatives or placed in the County's care due to parents'

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[6] C. William Swank Program in Rural-Urban Policy, Taking Measure of Ohio's Opioid Crisis, The Ohio State University (Oct. 2017) at 1.

[7] *Id.*

addiction. Young children have lost love ones and risk becoming the direct victims of overdoses themselves after coming into contact with opiates.

24. This human tragedy cannot be calculated or compensated. But the financial burden to the Plaintiffs is staggering. The Plaintiffs have expanded their services to confront this public health epidemic. Narcan administration has saved the lives of hundreds of its residents. The Plaintiffs have supported and developed programs to help combat the crisis. They would further expand these efforts, but the unprecedented epidemic exceeds budget capacity and has stretched existing programs thin. The Plaintiffs are also faced with increased costs of drug crimes and other public services because of the opioid epidemic.

25. Meanwhile, Defendants made blockbuster profits. In 2012 alone, opioids generated $8 billion in revenue for drug companies. By 2015, sales of opioids grew to approximately $9.6 billion. In the wake of an unprecedented public health epidemic, Defendants have not changed their ways or corrected their past misconduct, but instead are continuing to fuel the crisis.

26. Defendants' conduct has violated, and continues to violate, the Ohio Corrupt Practices Act ("OCPA"), R.C. § 2923.31 *et seq.*, and R.C. § 2307.60, which provides civil liability for injuring another through criminal acts. Additionally, Defendants' conduct constitutes a public nuisance, civil conspiracy, negligence, and unjust enrichment.

27. Accordingly, the Plaintiffs bring this action to hold Defendants accountable for their conduct and seek abatement, damages, and any other injunctive and equitable relief within this Court's powers to redress and halt these unfair, deceptive, and unlawful practices.

PARTIES

1. Plaintiffs

28. The County of Stark, Ohio ("the County") is a County organized under the laws of the State of Ohio. The County has its seat of government in Canton, Ohio. The Stark County

Prosecutor's Office is located at 110 Central Plaza South, Suite 510, Canton, Ohio 44702. The County provides many services for its residents, including public assistance, law enforcement services, criminal justice services, addiction and mental health services, and services for families and children.

29. The City of Canton is a municipality within Stark County, organized under the laws of the State of Ohio, with its seat of government located at 218 Cleveland Avenue S.W., Canton, Ohio 44702. The City of Canton brings this action by and through Kristen Bates Aylward, its Director of Law.

30. The City of Massillon is a municipality within Stark County, organized under the laws of the State of Ohio, with its seat of government located at 151 Lincoln Way East, Massillon, Ohio 44646. The City of Massillon brings this action by and through Andrea Scassa, its Director of Law.

31. The City of Alliance is a municipality within Stark County, organized under the laws of the State of Ohio, with its seat of government located at 504 East Main Street, Alliance, Ohio 44601. The City of Alliance brings this action by and through Jennifer L. Arnold, its Director of Law.

32. This action is also brought on behalf of the State of Ohio, by and through Stark County Prosecutor John D. Ferrero, City of Canton Director of Law, Kristen Bates Aylward, City of Massillon Director of Law, Andrea Scassa, and City of Alliance Director of Law, Jennifer L. Arnold with regard to the claims for statutory public nuisance in the name of the State of Ohio under R.C. § 3767.03 and R.C. § 4729.35.

33. Stark County and the Cities of Canton, Massillon, and Alliance (collectively, "Plaintiffs") provide many services for their residents, including public assistance, law

enforcement services, criminal justice services, addiction and mental health services, and services for families and children.

2. Defendants

34. Purdue Pharma, L.P. is a limited partnership organized under the laws of Delaware. Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. The Purdue Frederick Company Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. In 2007, Purdue and three of its executives pleaded guilty to federal criminal charges for deceptively marketing opioids. Rhodes Pharmaceuticals L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Coventry, Rhode Island. Purdue Pharma, L.P., Purdue Pharma, Inc., The Purdue Frederick Company Inc., and Rhodes Pharmaceuticals L.P. are collectively referred to as "Purdue."

35. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid and Dilaudid-HP, Butrans, and Hysingla ER in the United States and in Stark County.[8] OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2 and $3 billion. Nationwide, OxyContin constitutes roughly 25% of the entire market, by spending, for prescription opioids.

36. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA acquired Cephalon, Inc. in October 2011. Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva USA and Cephalon Inc. work together closely to market and sell Cephalon products in the United States and Stark County. Teva USA also sells generic opioids in

[8] Purdue also obtained approval to market Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride) in 2014, but it has not actively marketed it.

the United States and Stark County, including generic opioids previously sold by Allergan plc, whose generics business Teva Pharmaceutical Industries Ltd., Teva USA's parent company based in Israel, acquired in August 2016. Teva USA and Cephalon Inc. are collectively referred to as "Teva."

37. Teva manufactures, promotes, sells, and distributes opioids such as Actiq, a fentanyl lollipop, and Fentora, a dissolving pill, in the U.S. and Stark County. Actiq and Fentora have been approved by the U.S. Food and Drug Administration ("FDA") only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

38. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief,[9] J&J controls the sale and

[9] Unless otherwise noted, allegations based on "information and belief" are based on the uniformity of Defendants' nationwide strategy and practices, which would reasonably be expected to apply in Stark County in the same manner as elsewhere.

development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. These parties are collectively referred to as "Janssen."

39. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and Stark County, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

40. J&J imposes a "code of conduct" on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "Ethical Code for the Conduct of Research and Development," names only J&J and does not mention Janssen anywhere within the document. The "Ethical Code for the Conduct of Research and Development" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

41. Similarly, the "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "Pharmaceutical Companies of J&J" and as one of the "J&J Pharmaceutical Affiliates." It governs how "[a]ll employees of J&J Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise J&J Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case.

42. J&J made payments to thousands of physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-

marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

43. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. These parties are collectively referred to as "Endo."

44. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and Stark County. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Stark County, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. On July 6, 2017, in response to an FDA request that Endo voluntarily withdraw the product from the market, the company announced that it would stop marketing and selling a reformulated version of Opana ER that it had marketed as abuse-deterrent. *See infra*, Section F.2.

45. Mallinckrodt, plc is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt, plc describes itself as "a global specialty pharmaceuticals company" that "develops, manufactures, markets and distributes both branded and generic specialty pharmaceutical products and medical imaging agents." Although it has undergone name changes over time, Mallinckrodt, plc has a long history and describes itself as originally founded by Gustavo Mallinckrodt, Otto Mallinckrodt and Edward Mallinckrodt in 1867. Mallinckrodt plc also operates under the registered business name

Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri. Mallinckrodt Pharmaceuticals has responded to a letter from the FDA concerning Xartemis XR, and the Mallinckrodt Pharmaceuticals logo appears on marketing or purportedly educational materials. Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business in St. Louis, Missouri. Mallinckrodt, LLC is licensed to do business in Ohio as both a manufacturer and a wholesaler. Since June 28, 2013, it has been a wholly owned subsidiary of Mallinckrodt, plc. Prior to June 28, 2013 Mallinckrodt, LLC was a wholly-owned subsidiary of Covidien plc. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. Mallinckrodt, plc, Mallinckrodt, LLC, and SpecGx LLC are referred to as "Mallinckrodt."

46. Mallinckrodt manufactures, markets, and sells drugs in the United States including the branded drugs Exalgo and Xartemis XR. Mallinckrodt also has a large generics drug business, including hydrocodone- and oxycodone-combination products, morphine, methadone, hydromorphone, and fentanyl products. In July 2017, Mallinckrodt agreed to pay $35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

47. Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys' principal product and source of revenue is Subsys, a transmucosal immediate-release formulation ("TIRF") of fentanyl, contained in a single-dose spray device intended for oral sublingual administration. Subsys was approved by the FDA solely for the treatment of breakthrough cancer pain. In 2016, Insys made approximately $330 million in net revenue from Subsys. Insys promotes, sells, and distributes Subsys throughout the United

States and in the County. Insys' founder and owner was recently arrested and charged, along with other Insys executives, with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies. Other Insys executives and managers were previously indicted.

48. Defendants include the above referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the distribution, sale and/or dispensing of opioids.

49. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

50. For Defendant Jane Does 1 – 50, the Plaintiffs lack sufficient information to specifically identify the true names or capacities, whether individual, corporate, or otherwise, of these Defendants. The Plaintiffs will amend this Complaint to show their true names when they are ascertained.

JURISDICTION AND VENUE

51. This Court has jurisdiction over this matter pursuant to R.C. § 2305.01.

52. This Court has personal jurisdiction over all Defendants under R.C. § 2307.382 because the causes of action alleged in this Complaint arise out of each Defendants' transacting business in Ohio, contracting to supply services or goods in this state, causing tortious injury by an act or omission in this state, causing tortious injury in Ohio and because the Defendants and regularly do or solicit business or engage in a persistent course of conduct or deriving substantial revenue from goods used or consumed or services rendered in this state. Defendants have

purposefully directed their actions towards Ohio and/or have the requisite minimum contacts with Ohio to satisfy any statutory or constitutional requirements for personal jurisdiction.

53. The damages sought in this action exceed the amount of the exclusive original jurisdiction of the municipal courts.

54. The venue for this claim is proper in the Court of Common Pleas of Stark County under Ohio Civ. R. 3(B)(3), (6), and (7).

A. ADDITIONAL ALLEGATIONS COMMON TO ALL COUNTS

55. Until the mid-1990s, opioids were widely thought to be too addictive for use for chronic pain conditions, which would require long-term use of the drugs at increasingly high doses. For these conditions, the risks of addiction and other side effects outweighed any benefit from the drugs. Over the last two decades, Defendants turned that consensus on its head by falsely denying the risk of addiction and overstating the benefits of using opioids long-term.

56. Through marketing that was as pervasive as it was deceptive, Defendants convinced health care providers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven.

57. The result was that by the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. Defendants not only marketed opioids for chronic pain conditions, but also targeted primary care physicians (along with nurse practitioners and physician assistants), who were most likely to see patients with chronic pain conditions and least likely to have the training and experience to evaluate Defendants' marketing claims.

58. Defendants' deceptive marketing created a cadre of doctors who looked for pain and treated it with opioids, which created an even broader cohort of patients who expected and

received opioids. This laid the groundwork for today's epidemic of opioid addiction, injury, and death.

B. DEFENDANTS FALSELY TRIVIALIZED, MISCHARACTERIZED, AND FAILED TO DISCLOSE THE KNOWN, SERIOUS RISK OF ADDICTION.

59. Defendants spent hundreds of millions of dollars on promotional activities and materials, including advertising, websites, and in-person sales calls, that falsely denied or trivialized the risk of addiction and overstated the benefits of opioids. They also relied upon unsupported and misleading information derived from seminars, treatment guidelines, and other publications and programs by patient advocacy groups, professional associations, and physicians that seemed independent and therefore credible, but were actually funded and controlled by Defendants.

60. Defendants rely heavily on their sales representatives to convey their marketing messages and materials to prescribers in targeted, in-person settings. Not surprisingly, sales representatives from each of the Defendants visited prescribers in Stark County a total of 1,119 times and spent $91,784.81 on these visits from the third quarter of 2013 until the end of 2016. Sales representatives from Insys were the most frequent visitors to Stark County prescribers where there was a reimbursement reported, with at least 608 visits and payments totaling over $85,000, between the third quarter of 2013 and 2016. Purdue was the next most frequent visitor to the County, with 638 visits disclosed. Janssen, Mallinckrodt, and Teva also had 87, 30, and 37 visits, respectively. These visits likely understate the amount of "detailing" by each of the Defendants' sales representatives, as they reflect only visits in which some sort of payment was provided.

61. To ensure that sales representatives deliver the desired messages to prescribers, Defendants direct and monitor their sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' notes (known as

"call notes") from each visit. Defendants likewise required their sales representatives to use sales aids reviewed, approved, and supplied by the companies. They further ensured marketing consistency nationwide through national and regional sales representative training. For example, Purdue provided multi-week trainings for sales representatives at its headquarters in Connecticut, followed by field training in the target area with more seasoned representatives.[10] Thus, the companies' sales forces in Stark County carried out national marketing strategies, delivering centrally scripted messages and materials that were consistent across the country.

62. In addition, Purdue recruited and paid respected health care professionals as "speakers" who presented Purdue-approved programs to other prescribers at lunch and dinner events. From 1996 to 2001, Purdue held more than 40 national conferences and more than 5,000 physicians, pharmacist, and nurses attended these speaker conferences. In addition to speaker programs, Purdue targeted doctors with "educational" programing and funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants by July 2002.

63. Purdue was not alone in using this tactic. Defendants cooperated in using "key opinion leaders" ("KOLs")—experts in the field who were especially influential because of their reputations and seeming objectivity—to deliver paid talks and continuing medical education programs (or "CMEs") that provided information about treating pain and the risks, benefits, and use of opioids. These KOLs received substantial funding and research grants from these Defendants, and the CMEs were often sponsored by Defendants—giving them considerable influence over the messenger, the message, and the distribution of the program. Only doctors supportive of the use and safety of opioids for chronic pain received these funding and speaking

[10] Declaration of Sean Thatcher, filed in *State of Montana v. Purdue Pharma L.P. et al.*, No. ADV-2017-949 (Mont. 1st Judicial Dist. Ct., Lewis & Clark County).

opportunities, which were not only lucrative, but also helped doctors build their reputations and bodies of work. One notable KOL, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected "misinformation" and were "clearly the wrong thing to do."

64. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Pain Foundation and the American Pain Society, that were also able to exert greater influence because of their seeming independence. Defendants exerted influence over these groups by providing major funding directly to them, as well. These "front groups" for the opioid industry put out patient education materials and treatment guidelines that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. In many instances, these Defendants distributed these publications to prescribers or posted them on their websites.

65. The FDA does not regulate all of the conduct in which the Defendants engaged. For example, drug labels do not address the use of opioids in treating specific conditions such as lower back pain, headaches, or fibromyalgia, three conditions for which opioids are ineffective, but for which Purdue and, upon information and belief, the other Defendants, marketed their drugs. The FDA also does not regulate unbranded advertising. Likewise, the FDA does not regulate marketing funneled through third-parties.

66. Neither the third-party, unbranded materials, nor the marketing messages or scripts relied on by Defendants' sales representatives, were reviewed or approved by the FDA. Upon information and belief, all of the messages described below were disseminated to Stark County prescribers and patients through sales representative visits, medical education programs, marketing materials, websites, or other sources.

1. Minimizing or mischaracterizing the risk of addiction

67. To convince prescribers and patients that opioids are safe, Defendants deceptively represented that the risk of abuse and addiction is modest and manageable and limited to illegitimate patients, not those with genuine pain. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted, (2) patients at greatest risk of addiction could be identified, and (3) all other patients could safely be prescribed opioids.

68. Defendants also undermined evidence that opioids are addictive by omitting discussion of addiction, or by promoting a particular drug as less likely to be abused.

69. Defendants also failed to disclose to prescribers, including, upon information and belief, in Stark County, the difficulty of withdrawing from opioids. For example, a 2011 non-credit educational program sponsored by Endo, entitled Persistent Pain in the Older Adult, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's opioid dose over ten days. However, this claim is at odds with the experience of patients addicted to opioids. Most patients who are dependent upon or addicted to opioids will experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

70. For example, Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management,* which taught that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not disclose the significant hardships that often accompany cessation of use, even when gradually tapering off.

71. A 2010 Purdue "Training Guide for Healthcare Providers" on OxyContin claimed that patients who were physically dependent on opioids, but who had not developed an "addiction disorder" "[c]an generally discontinue their medicine with mild to no withdrawal syndrome once their symptoms are gone by gradually tapering the dosage according to their doctor's orders."

72. Defendants falsely portrayed "true" addiction in its narrowest form. For example, *Providing Relief, Preventing Abuse*, a pamphlet published by Purdue in 2011 for prescribers and law enforcement, shows pictures of the signs of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa—under the heading "Indications of Possible Drug Abuse." These depictions misleadingly reassured doctors that, in the absence of those extreme signs, they need not worry that their patients are abusing or addicted to opioids. But Purdue knew that individuals who resort to these extremes are uncommon; they far more typically become dependent and addicted through oral use. According to briefing materials Purdue submitted to the FDA in October 2010, OxyContin was used non-medically by injection as little as 4% of the time. Purdue made *Providing Relief, Preventing Abuse* available to sales representatives to show to or leave with prescribers, including, on information and belief, prescribers in Stark County.

73. Purdue also disseminated misleading information about opioids and addiction through the American Pain Foundation ("APF"), over which Purdue and other Defendants exercised control.[11] For example, *A Policymaker's Guide to Understanding Pain & Its*

[11] In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings, suggested activities and publications for APF to pursue, which they then funded APF to pursue. Purdue was APF's second-biggest donor. The largest donor, from 2007 until APF closed its doors in 2012, was Endo, which provided more than half of APF's $10 million in total funding during that time period. Purdue grant letters informed APF that Purdue's contributions reflected the company's effort to "strategically align its investments in nonprofit organizations that share [its] business interests." Purdue also engaged APF as a paid consultant on various initiatives and deployed APF to lobby

Management, a 2011 APF publication that Purdue sponsored, claimed that pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction." This guide also asserted, without basis, that "less than 1% of children treated with opioids become addicted" and perpetuated the concept of pseudoaddiction (*see* Section A.2, *infra*). Purdue provided substantial funding to APF and closely collaborated with APF in creating *A Policymaker's Guide.* On information and belief, based on Purdue's close relationship with APF and the periodic reports APF provided to Purdue about the project, Purdue had editorial input into *A Policymaker's Guide.* It is still available to Stark County prescribers online.

74. Purdue also maintained a website from 2008 to 2015, *In the Face of Pain*, that downplayed the risks of chronic opioid therapy. Purdue deactivated this website in October 2015 following an investigation by the New York Attorney General. *In the Face of Pain* asserted that policies limiting access to opioids are "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. While a document linked from the website briefly mentioned opioid abuse, the site itself *never* mentioned the risk of addiction. At the same time, the website contained testimonials from several dozen physician "advocates" speaking positively about opioids. Eleven of these advocates received a total of $231,000 in payments from Purdue from 2008 to 2013—a fact notably omitted from the site.

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for its interests on Capitol Hill, for example, by opposing legislation that would have restricted the use of long-acting (but not short-acting) opioids, which would distinctly disadvantage Purdue.

The close relationship between APF and Purdue was not unique, but mirrors relationships between APF and Defendants. APF's clear lack of independence—in its finances, management, and mission—and its willingness to allow Defendants to control its activities and messages support an inference that each Defendant that worked with it was able to exercise editorial control over its publications.

75. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

76. Endo also distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website, www.opana.com.

77. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain."

78. Janssen currently runs a website, *Prescriberesponsibly.com*, which claims that concerns about opioid addiction are "overestimated."

79. Until at least June 2007, Mallinckrodt gave education grants to pain-topics.org, a now defunct website that proclaimed to be an organization "dedicated to offering contents that are evidence-based, unbiased, non-commercial, and comply with the highest standards and principles of accrediting and other oversight organizations."

80. Among its content, the website contained a handout titled *Oxycodone Safety for Patients*, released in June 2007, which advised doctors that "[p]atients' fears of opioid addiction should be dispelled."[12] The handout misleadingly stated that "[a]ddiction to oxycodone in persons

[12] Lee A. Kral, *Commonsense Oxycodone Prescribing & Safety*, http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.

without a recent history of alcohol or drug problems is rare." It also misleadingly characterized withdrawal symptoms as occurring only if medication is suddenly stopped and suggested that gradually lowering the dose as a way to "help prevent" withdrawal symptoms, which the handout characterized mildly as merely "uncomfortable" symptoms that may include "diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings." This handout is still available to prescribers and patients today.

81. Purdue and Endo also sponsored APF's *Exit Wounds* (2009), which targeted veterans and misleadingly portrayed addiction as resulting only from recreational use or other intentional abuse of opioids and misleadingly suggested that patients using the drugs as prescribed would not become addicted, or even experience withdrawal symptoms upon discontinuing the drugs, unless their dosage were stopped or lowered too abruptly:

> Physical dependence means that a person will develop symptoms and signs of withdrawal (e.g., sweating, rapid heart rate, nausea, diarrhea, goose bumps, or anxiety) if a drug medication is suddenly stopped or the dose is lowered too quickly. . . . Physical dependence is normal. This does not mean you are addicted. Opioid medications can, however, be abused or used as recreational drugs, and some people who use drugs in this way *will* become addicted. Addiction is a disease state in which people can no longer control their use of a drug that is causing them harm.

82. Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." Mallinckrodt describes C.A.R.E.S as its own advocacy program, and promised "[t]hrough the C.A.R.E.S. Alliance website, prescribers and pharmacists can access tools and resources to assist them in managing the risks of opioid pain medications, and patients can find information designed to help them better manage their pain and understand the responsible use of the medications they take."

83. The C.A.R.E.S. Alliance publicly describes itself as "[c]reated with leading pain experts through a scientific process" and offering "free resources" to "promote safe prescribing, dispensing, use, storage, and disposal" of opioid pain medications. It further described the "safe-use programs and voluntary tools" it developed as "grounded in science and research." The "C.A.R.E.S. Alliance" itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

84. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!*. This book is still available online in the County and elsewhere. The false claims and misrepresentations in this book include the following statements:

- "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "[O]pioid medication may also significantly relieve many patients' chronic pain. Over the past decade, lots of good scientific studies have shown that long-acting opioids can reduce the pain in some patients with low back pain, neuropathic pain, and arthritis pain."
- "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."
- "[P]hysical dependence . . . is a normal bodily reaction that happens with lots of different types of medications, including medications not used for pain, and is easily remedied."
- "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."
- "[I]n our experience, the issue of tolerance is overblown."
- "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."

- "**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

- "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

- "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

85. Mallinckrodt's former parent Company, Covidien, published a patient resource, "Opioid Safe Use and Handling Guide," which stated that: "Addiction does not often develop when taking opioid pain medicine as prescribed under the guidance of a healthcare provider, but it can occur;" and "Taking more than your prescribed amount of medication to treat your pain is not the same as addiction, but it can be very dangerous."

86. Defendants' efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. Studies have shown that at least 8-12%, and as many as 30-40% of long-term users of opioids experience problems with addiction. Addiction can result from the use of any opioid, "even at recommended dose"[13] and the risk increases with chronic (more than three months) use.

2. Defendants Falsely Described Addiction as Pseudoaddiction and Dangerously Encouraged Doctors to Respond by Prescribing More Opioids.

87. Defendants covered up the occurrence of addiction by attributing it to a made-up condition they called "pseudoaddiction." This concept taught that signs of addiction, including

[13] *FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics,* FDA (Sept. 10, 2013); *see also FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death,* FDA (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel.

88. For example, a 2010 Purdue "Training Guide for Healthcare Providers" on OxyContin taught that "[b]ehaviors that suggest drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior."

89. Purdue also disseminated the Definitions Related to the Use of Opioids for the Treatment of Pain section of a "consensus statement" published by the American Pain Society ("APS"), which Purdue heavily funded. Purdue disseminated this definition though Purdue's unbranded *Partners Against Pain* website.[14] APS defined pseudoaddiction in the same terms endorsed by Purdue:

> Physical dependence, tolerance, and addiction are discrete and different phenomena that are often confused.... Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may "clock watch," and may otherwise seem inappropriately "drug seeking." Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated. Physical dependence on and tolerance to prescribed drugs do not constitute sufficient evidence of psychoactive substance use disorder or addiction. They are normal responses that often occur with the persistent use of certain medications....A patient who is physically dependent on opioids may sometimes continue to use these despite resolution of pain only to avoid withdrawal. Such use does not necessarily reflect addiction.

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[14] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and medical education resources distributed to prescribers by the sales force. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

90. Purdue, through its unbranded imprint *Partners Against Pain*, promoted the concept of pseudoaddiction through at least 2013 on its website.

91. Purdue directly disseminated materials about "pseudoaddiction" through a brochure entitled *Providing Relief, Preventing Abuse*. The 2008 edition of *Providing Relief, Preventing Abuse* explained that the term "pseudoaddicton"

> describes the misinterpretation by members of the health care team of relief-seeking behaviors in a person whose pain is inadequately treated as though they were drug-seeking behaviors as would be common in the setting of abuse. The lack of appropriate response to the behaviors can result in an escalation of them by the patient, in an attempt to get adequate analgesia.

92. The 2008 edition of *Providing Relief, Preventing Abuse* further explained that "[p]seudoaddiction can be distinguished from addiction in that the behaviors resolve when pain is effectively treated."

93. By 2011, Purdue had revised the brochure, and the second edition of *Providing Relief, Preventing Abuse* explained that:

> Some patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate. The term *pseudoaddiction* has emerged in the literature to describe the inaccurate interpretation of these behaviors in patients who have pain that has not been effectively treated. Pseudoaddiction behaviors can be distinguished from addiction by the fact that, when adequate analgesia is achieved, the patient who is seeking pain relief demonstrates improved function, uses the medications as prescribed, and does not use drugs in a manner that persistently causes sedation or euphoria.

94. The 2014 edition of *Providing Relief, Preventing Abuse* dropped the term "pseudoaddiction" but included an "Other Considerations" section that stated that "[s]ome patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate. Such behaviors may occur occasionally even with successful opioid therapy for pain; a pattern of persistent occurrences should prompt concern and further assessment."

95. The Federation of State Medical Boards ("FSMB"), a trade organization representing the State Medical Board of Ohio as well as others, finances opioid- and pain-specific programs through grants from the Defendants. A 2004 version of the FSMB *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), and the 2007 book adapted from them, *Responsible Opioid Prescribing*, advanced the concept of pseudoaddiction.

96. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo, and Teva. The FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally, including, upon information and belief, in Ohio.

97. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when *pain is under-treated* . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until May 2012.

98. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC, an initiative run by the APF, by funding NIPC projects; developing, specifying, and reviewing its content; and distributing NIPC materials. APF internal documents show that APF viewed the NIPC as an "opportunity to generate new revenue" given Endo's funding commitment.

99. Defendants also promoted the concept of pseudoaddiction through Dr. Russell Portenoy, a leading KOL for the Defendants. In doing so, he popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

100. The FAQs section of pain-topics.org, a now-defunct website to which Mallinckrodt provided funding, also contained misleading information about pseudoaddiction. Specifically, the website advised providers to "keep in mind" that signs of potential drug diversion, rather than signaling "actual" addiction, "may represent pseudoaddiction," which the website described as behavior that occurs in patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications and may be erroneously perceived as 'drug seeking.'"

101. The CDC Guideline for prescribing opioids for chronic pain, a "systematic review of the best available evidence" by a panel excluding experts without conflicts of interest, rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,"[15] and that physicians should "reassess pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[16]

3. Overstating the efficacy of screening tools.

102. Defendants falsely instructed prescribers and patients that screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of

[15] CDC Guideline at 13.

[16] *Id.* at 25.

evidence that these strategies actually work to mitigate addiction risk. By using screening tools, these Defendants advised doctors that they could identify patients likely to become addicted and safely prescribe to everyone else.

103. Such misrepresentations regarding safe opioid prescribing made health care providers more comfortable prescribing opioids to their patients and patients more comfortable starting chronic opioid therapy. These misrepresentations were especially insidious because these Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Moreover, these misrepresentations allowed doctors to believe opioid addiction was the result of other prescribers failing to rigorously manage and weed out problem patients, not a risk inherent to the drugs.

104. Defendants conveyed these safe prescribing messages through their in-person sales calls to doctors, including, upon information and belief, in the County based on the uniformity of their nationwide marketing strategy and training of sales representatives.

105. Defendants also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences, which would have been attended by and were available online, to Stark County prescribers.

106. For example, Purdue sponsored a 2011 CME program titled Managing Patient's Opioid Use: Balancing the Need and Risk. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths." Purdue also funded a 2012 CME program called Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

107. Purdue used its involvement in the College on the Problems of Drug Dependence ("CPDD"), which promotes scientific research and professional development to support addiction prevention professionals, to promote the idea that addiction risk can be managed. A Purdue employee served on the CPDD board of directors. Purdue presented a disproportionate number of talks—with very different messages from non-Purdue talks—at CPDD conferences. One of Purdue's consistent themes is that "bad apple" patients, not opioids, are the source of the opioid crisis, and that once those patients are identified doctors can safely prescribe opioids without a risk of addiction. Hundreds of addiction treatment specialists from across the country and, upon information and belief, prescribers from Stark County, attended these conferences.

108. Endo paid for a 2007 supplement in the Journal of Family Practice written by a doctor who became a member of Endo's speakers bureau (doctors paid to give talks, typically reserved for the largest prescribers) in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

109. The CDC Guideline confirmed the falsity of Defendants' claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognized that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and

counseled that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[17]

C. DEFENDANTS OVERSTATED THE BENEFITS OF CHRONIC OPIOID THERAPY WHILE FAILING TO DISCLOSE THE LACK OF EVIDENCE SUPPORTING LONG-TERM USE.

1. Mischaracterizing the benefits of and evidence for long-term use.

110. To convince prescribers and patients that opioids should be used to treat chronic pain, Defendants had to persuade them of a significant upside to long-term opioid use. Assessing existing evidence, the CDC Guideline found that there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain."[18] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)"[19] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."[20] As a result, the CDC recommends that opioids not be used in the first instance for treatment of chronic pain; rather, opioids should be used only after prescribers have exhausted alternative treatments. Likewise, the Ohio Guidelines for Prescribing Opioids for the Treatment of Chronic Non-Terminal Pain 80 mg of a Morphine

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[17] CDC Guideline at 28 (emphasis added).

[18] *Id.* at 10.

[19] *Id.* at 9.

[20] Letter from Janet Woodcock, M.D, Dir., Center for Drug Eval. and Research, to Andrew Kolodny, M.D. (Sept. 10, 2013).

Equivalent Daily Dose (MED) "Trigger Point," released in October 2013, call for providers to consider non-opioid therapies first.[21]

111. That has not changed. Indeed, a recent study found that "the use of opioid vs nonopioid medication therapy did not result in significantly better pain-related function over 12 months." These results did "not support initiation of opioid therapy for moderate to severe chronic back pain or hip or knee osteoarthritis pain."[22]

112. Nevertheless, Defendants touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence.

113. In addition, two prominent professional medical membership organizations, the APS and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Defendants. Upon information and belief, Defendants exercised considerable influence over their work on opioids. Both organizations issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was at the time a paid speaker for Purdue and later became a senior executive for the company. KOL Dr. Portenoy was the sole consultant. The consensus

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[21] http://mha.ohio.gov/Portals/0/assets/Initiatives/GCOAT/Guidelines-Chronic-Pain.pdf

[22] Krebs EE, Gravely A, Nugent S, et al. Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain: The SPACE Randomized Clinical Trial. *JAMA*. 2018;319(9):872–882. doi:10.1001/jama.2018.0899, *available at* https://jamanetwork.com/journals/jama/article-abstract/2673971?redirect=true

statement remained on AAPM's website until 2011 and was only removed from AAPM's website after a doctor complained.

114. A past president of the AAPM, Dr. Scott Fishman, who also served as a KOL for the Defendants, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[23]

115. AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines, like the AAPM/APS Guidelines, were particularly important to the Defendants in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Six of the twenty-one panel members who drafted the AAPM/APS Guidelines received support from Purdue, eight from Teva, nine from Janssen, and ten from Endo.

116. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

[23] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), available at http://www.medscape.org/viewarticle/500829.

117. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

118. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain*, and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited at least 1,833 times in academic literature.

119. Purdue, for example, also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions. One study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, involved providing oxycodone for 30 days, and then randomizing participants and providing a placebo, an immediate release oxycodone with acetaminophen (like Percocet), or OxyContin. Only 107 of the 167 patients went on to the second phase of the study, and most who withdrew left because of adverse events (nausea, vomiting, drowsiness, dizziness, or headache) or ineffective treatment. Despite relating to a chronic condition, opioids were provided only short-term. The authors even acknowledge that the "results . . . should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis]."[24] Yet, the authors conclude that "[t]his clinical experience shows that opioids were well tolerated with only rare

[24] Jacques R. Caldwell, *et al.*, *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 266.4 Journal of Rheumatology 862-869 (1999).

incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term."[25] This statement is not supported by the data—a substantial number of patients dropped out because of adverse effects, there was no reported data regarding addiction, and the study was not long-term.

120. Teva deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals.

121. Both Actiq and Fentora are extremely powerful fentanyl-based opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Teva from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risks of "serious and life-threatening adverse events" and abuse—which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

122. Despite this, Teva has conducted a well-funded and deceptive campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Teva used CMEs, speaker programs, KOLs, journal supplements, and "detailing" visits by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain, without disclosing the lack of evidence or the FDA's rejection of their use for chronic pain.

[25] *Id.*

123. For example, Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

124. Teva's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

125. In December 2011, Teva widely disseminated a journal supplement entitled *"Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)"* to Anesthesiology News, Clinical Oncology News, and Pain Medicine News—three publications that are sent to thousands of anesthesiologists and other medical professionals nationally, including, upon information and belief, in Stark County. The Special Report openly promotes Fentora for "multiple causes of pain," and not just cancer pain.

126. Teva's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but also were approved by the FDA for such uses.

127. On December 28, 2011, the FDA mandated a Risk Evaluation and Mitigation Strategy (REMS) for the class of products for which Teva's Actiq and Fentora belong, Transmucosal Immediate Release Fentanyl (TIRF). The TIRF REMS programs include mandatory patient and prescriber enrollment forms, as well as certification requirements for prescribers. The forms are not comprehensive and do not, for instance, disclose that addiction can

develop when prescribed as directed, nor do they disclose that risks are greatest at higher doses—and patients must already be taking high doses of opioids to be prescribed Actiq and Fentora.

2. Overstating opioids' effect on patients' function and quality of life

128. Defendants also claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs.

129. Defendants' materials that, upon information and belief, were distributed or made available in Stark County reinforced this message. The 2011 publication *A Policymaker's Guide* falsely claimed that "multiple clinical studies have shown that opioids are effective in improving" "[d]aily function" and "[o]verall health-related quality of life for people with chronic pain." A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively. Similarly, since at least May of 2011, Endo has distributed and made available on its website, opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement.

130. Additional illustrative examples are described below:

a. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as "a fact" that "opioids may make it *easier* for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

b. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

c. Purdue and Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in May 2012.

d. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make claims of functional improvement, and Endo closely tracked visits to the site.

e. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

131. Mallinckrodt followed suit, stating on its website, in a section on "responsible use" of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[26]

132. Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions

[26] Mallinckrodt Pharmaceuticals, Responsible Use, http://www.mallinckrodt.com/corporate-responsibility/responsible-use

(depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

133. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[27] Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures.

134. Yet, Defendants targeted these patients. For example, a former sales representative recently explained that he was directed to market Purdue's OxyContin for chronic pain, including lower back pain and pain from arthritis, and to focus prescribers on patients with pain that prevented them from working or functioning day to day.[28]

135. The FDA and other federal agencies have, for years, made clear the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life.[29]

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[27] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), available at http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse?

[28] Declaration of Sean Thatcher, filed in *State of Montana v. Purdue Pharma L.P. et al.*, No. ADV-2017-949 (Mont. 1st Judicial Dist. Ct., Lewis & Clark County).

[29] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been

The CDC Guideline, following a "systematic review of the best available evidence," concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[30] According to the CDC director, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[31] The Ohio Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain 80 mg of a Morphine Equivalent Daily Dose (MED) "Trigger Point" similarly state that "[p]roviders should avoid starting a patient on long-term opioid therapy when treating chronic pain."

136. Similarly, analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000.00, stemming from greater side effects and slower returns to work. According to these studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later.

3. Omitting or mischaracterizing adverse effects of opioids.

137. In materials Defendants produced, sponsored, or controlled, these Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or nonsteroidal anti-inflammatory drugs (or NSAIDs, like ibuprofen). None of these claims were corroborated by scientific evidence.

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demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[30] CDC Guideline at 2, 18.

[31] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).

138. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and death, Defendants routinely ignored other risks, such as hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy,"[32] in which the patient becomes more sensitive to pain over time; hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (conditions that often accompany chronic pain symptoms).

139. Purdue and Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure is approximately 3,200—far fewer than from opioids).[33] This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

140. Purdue and Endo also sponsored APF's *Exit Wounds* (2009), a book aimed at veterans. This book omits warnings of the potentially fatal risk of interactions between opioids and benzodiazepines, a class of drug commonly prescribed to veterans with post-traumatic stress disorder. This book is available from Amazon.com and other retailers. More than 28,000 veterans live in Stark County, which is home to more veterans than any other County in the State.

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[32] *See* n. 20, *supra*.

[33] The higher figure reflects deaths from all causes.

141. Purdue and Endo sponsored a CME program, *Overview of Management Options*, published by the American Medical Association in 2003, 2007, 2010, and 2013, and discussed further below. The CME was edited by Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

142. Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of NSAIDs. These Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (*See e.g.*, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) [describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids]; *Finding Relief: Pain Management for Older Adults* (Janssen) [NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation].)

143. These omissions are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22.9% of patients in opioid trials dropped out before the study began because of the "intolerable effects" of opioids.[34]

144. Again, Defendants' misrepresentations were effective. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%. The CDC reports that the quantity of opioids dispensed per capita tripled from 1999 to 2015.

[34] Meredith Noble M, *et al.*, *Long- Term Opioid Management for Chronic Noncancer Pain (Review)*, Cochrane Database of Systematic Reviews, Issue 1, 11 (2010).

D. DEFENDANTS CONTINUED TO TELL DOCTORS THAT OPIOIDS COULD BE TAKEN IN EVER-HIGHER DOSES WITHOUT DISCLOSING THEIR GREATER RISKS.

145. Defendants falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. These Defendants needed to generate a comfort level among doctors to ensure the doctors maintained patients on the drugs even at the high doses that became necessary. Further, as described in more detail in Section E, Purdue encouraged doctors to prescribe higher doses, rather than prescribe OxyContin more frequently than twice-a-day—despite knowing that OxyContin frequently did not provide 12 hours of relief.

146. Purdue-sponsored publications and CMEs available online also misleadingly suggested that higher opioid doses carried no added risk.

147. Through at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor did not prescribe a sufficient dose of opioids, the patient should see different doctors until finding a doctor who would.

148. *A Policymaker's Guide,* the 2011 publication on which, upon information and belief, Purdue collaborated with APF, taught that dose escalations are "sometimes necessary," but it did not disclose the risks from high dose opioids. This publication is still available online.

149. The Purdue-sponsored CME, *Overview of Management Options*, discussed above, again instructed physicians that NSAIDs (like ibuprofen) are unsafe at high doses (because of risks to patients' kidneys), but it did not disclose risks from opioids at high doses.

150. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

151. Endo distributed a pamphlet edited by Dr. Russell Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which appeared on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

152. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

153. These claims conflict with the scientific evidence. Patients receiving high doses of opioids (*e.g.*, doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.

154. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent."[35] That is why the CDC advises doctors to

[35] CDC Guideline at 19. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

"avoid increasing dosages" above 90 mg MED.[36]

E. PURDUE MISLEADINGLY PROMOTED OXYCONTIN AS SUPPLYING 12 HOURS OF PAIN RELIEF WHEN PURDUE KNEW THAT, FOR MANY PATIENTS, IT DID NOT.

155. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch.

156. OxyContin has been FDA-approved for twice-daily—"Q12"—dosing frequency since its debut in 1996. Purdue sought that dosing frequency in order to maintain a competitive advantage over more frequently dosed opioids. Even so, Purdue has gone well beyond the label's instructions to take OxyContin every 12 hours. Purdue has affirmatively claimed in its general marketing and, upon information and belief, to prescribers in Stark County that OxyContin lasts for 12 hours and that this is a key advantage of OxyContin, implying that most or all patients would in fact experience continuous pain relief for the full 12 hour dose period. Purdue has also failed to disclose that OxyContin fails to provide 12 hours of pain relief to many patients. These misrepresentations, which Purdue continues to make, are particularly dangerous because inadequate dosing helps fuel addiction, as explained below.

157. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night." But the FDA has never approved such a marketing claim. To the contrary, the FDA found in 2008, in response to a Citizen

[36] CDC Guideline at 16.

Petition by the Connecticut Attorney General, that a "substantial portion" of chronic pain patients taking OxyContin experienced "end of dose failure"—*i.e.,* little or no pain relief at the end of the dosing period.

158. Moreover, Purdue itself long has known, dating to its development of OxyContin, that the drug wears off well short of 12 hours in many patients. In one early Purdue clinical trial, a third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental painkillers—"rescue doses"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once. In other research conducted by Purdue, the drug wore off in under 6 hours in 25% of patients and in under 10 hours in more than 50%.

159. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[37] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

160. Purdue has remained committed to 12-hour dosing because it is key to OxyContin's market dominance and comparatively high price; without this advantage, the drug had little to offer over less expensive, short-acting opioids. In a 2004 letter to the FDA, Purdue acknowledged that

[37] Harriet Ryan, "'*You Want a Description of Hell?' OxyContin's 12-Hour Problem*," Los Angeles Times, May 5, 2016, available at http://www.latimes.com/projects/oxycontin-part1/.

it had not pursued approval to allow more frequent dosing in the label (*e.g.*, every 8 hours) because 12-hour dosing was "a significant competitive advantage."

161. While Purdue's commitment to marketing opioids as a 12-hour drug made it more addictive, Purdue falsely promoted OxyContin as providing "steady state" relief and less likely than other opioids to create a cycle of crash and cravings that fueled addiction and abuse.

162. Promotion of 12-hour dosing, without disclosing its limitations, is misleading because it implies that the pain relief supplied by each dose lasts 12 hours. FDA approval of OxyContin for 12-hour dosing does not give Purdue license to misrepresent the duration of pain relief it provides to patients; moreover, Purdue had a responsibility to correct its label to reflect appropriate dosing and to disclose to prescribers what it knew about OxyContin's actual duration, but disregarded that responsibility in its pursuit of a marketing advantage.[38]

163. Purdue was also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence. Purdue's promoted solution to this problem was either to stop mentioning it, or to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks—including increased danger of addiction, overdose, and death. It means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 MED that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[39]

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[38] For example, Kadian, an opioid manufactured by Allergan, was designed to be taken once a day, but the label acknowledges and advises dosing of up to every 12 hours for certain patients.

[39] CDC Guideline at 16.

F. PURDUE AND ENDO OVERSTATED THE EFFICACY OF ABUSE-DETERRENT OPIOID FORMULATIONS AND MALLINCKRODT DECEPTIVELY MARKETED BRANDED OPIOIDS AS ABUSE-DETERENT.

164. Rather than take the widespread abuse and addiction to opioids as reason to cease their untruthful marketing claims and efforts, Defendants Purdue and Endo seized them as a market opportunity. These companies oversold their abuse-deterrent formulations ("ADF") as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids. Purdue's and Endo's false and misleading marketing of the benefits of its ADF opioids preserved and expanded their sales and influenced prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids—thereby prolonging the opioid epidemic in Stark County.

1. Purdue's Deceptive Marketing of Reformulated OxyContin and Hysingla ER.

165. Reformulated ADF OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a Citizen Petition filed by Purdue, permitted reference to the abuse-deterrent properties in its label. However, the FDA made clear that abuse-deterrent properties do not stop tampering but only make it harder to modify the pills. ADF pills can still be snorted and injected if tampered with, and these pills are still sought after by abusers because of their high likability when snorted. Further, ADF properties do not reduce oral abuse—the most common form of abuse—in any way. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties and limitations.

166. It is unlikely a coincidence that reformulated OxyContin was introduced shortly before generic versions of OxyContin were to become available, threatening to erode Purdue's market share and the price it could charge. Through a Citizen Petition, Purdue was able to secure a determination by the FDA in April 2013 that original OxyContin should be removed from the market as unsafe (lacking abuse-deterrent properties), and thus non-ADF generic copies could not

be sold. As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires.

167. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis. Touting the benefits of ADF opioids, Purdue's website asserts, for instance: "we are acutely aware of the public health risks these powerful medications create . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . ."[40]

168. Ironically, Purdue sales representatives also regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids, including, upon information and belief, in Stark County. Specifically, Purdue sales representatives:

a. claimed that Purdue's ADF opioids prevent tampering and that its ADFs could not be crushed or snorted;

b. claimed that Purdue's ADF opioids reduce opioid abuse and diversion;

c. asserted or suggested that Purdue's ADF opioids are safer than other opioids; and

d. failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

169. These misrepresentations and omissions are misleading and contrary to Purdue's labels.

170. Purdue trained its sales representatives to discuss OxyContin's abuse-deterrent formulation. A former Purdue sales representative in Montana, who had been trained by Purdue,

[40] Purdue website, *Opioids With Abuse-Deterrent Properties*, available at http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrentproperties/.

recalled that he often discussed OxyContin's abuse-deterrent formulation with prescribers who were reluctant to prescribe opioids.[41]

171. After Purdue launched reformulated OxyContin, sales increased nationwide.[42]

172. Purdue knew or should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin"[43] and is still regularly tampered with and abused.

173. Websites and message boards used by drug abusers, such as bluelight.org and reddit.com, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. A publicly available Citizen Petition submitted to the FDA in 2016 by a drug manufacturing firm challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily prepare so-called abuse deterrent OxyContin to be snorted or injected. Opioid addicts in Stark County also, upon information and belief, continued to crush, snort, and inject abuse-deterrent formulations of their drugs, including OxyContin and Opana ER.

174. *One-third* of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, there was no meaningful reduction in drug abuse, as many addicts simply shifted to other drugs such as heroin.

175. A 2013 article presented by Purdue employees based on review of data from poison control centers, concluded that ADF OxyContin can reduce abuse, but ignored important negative

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[41] Declaration of Sean Thatcher, filed in *State of Montana v. Purdue Pharma L.P. et al.*, No. ADV-2017-949 (Mont. 1st Judicial Dist. Ct., Lewis & Clark County).

[42] *Id.*

[43] *In re OxyContin*, 1:04-md-01603-SHS, Docket No. 613, Oct. 7, 2013 hr'g, Testimony of Dr. Mohan Rao, 1615:7-10.

findings. The study revealed that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids (including heroin) after the reformulation of OxyContin. In short, the article deceptively emphasized the advantages and ignored the disadvantages of ADF OxyContin.

176. The CDC Guideline confirms that "*[n]o* studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[44] Tom Frieden, the Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death."[45]

177. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated OxyContin has a meaningful impact on abuse."[46] Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

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[44] CDC Guideline at 22 (emphasis added).

[45] Matthew Perrone, *Drugmakers Push Profitable, but Unproven, Opioid Solution*, Assoc. Press (Jan. 2, 2017), available at http://www.detroitnews.com/story/news/nation/2017/01/02/painkillers-drugmakers-addictive/96095558.

[46] Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

178. Despite the qualifying language in Purdue's label and its own evidence—and lack of evidence—regarding the impact of its ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers.

2. Endo's Deceptive Marketing of Reformulated Opana ER.

179. In a strategy that closely resembled Purdue's, Endo, as the expiration of its patent exclusivity for Opana ER neared, and aware that it needed to be able to compete with other opioids, like OxyContin, that were being introduced as ADFs, also made abuse-deterrence a key to its marketing strategy.

180. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant. Even prior to its approval, the FDA advised Endo in January 2011 that it could not market new Opana ER as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse."[47] In other words, Opana ER was still crushable. Indeed, in its approval package, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."

181. Nonetheless, in August of 2012, Endo submitted a confidential Citizen Petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted, and that it was resistant to "aqueous extraction," or injection by syringe. Borrowing a page from Purdue's playbook, Endo announced

[47] Attorney General of the State of New York, *In the Matter of Purdue Pharma L.P.*, Assurance No.: 15-151, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 5.

it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse deterrence). That would prevent generic copies of original Opana ER from competitors, such as Impax Laboratories ("Impax"), which had sought approval to sell a generic version of the drug.

182. Endo then sued the FDA, seeking to force expedited consideration of its Citizen Petition. The court filings confirmed Endo's true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, which Endo spent on developing the reformulated drug to "promote the public welfare" would be lost.[48] The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."[49]

183. Despite Endo's purported concern with public safety, not only did Endo continue to distribute original Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo also claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[50]

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[48] Plaintiff's Opposition to Defendants' and Intervenor's Motions to Dismiss and Plaintiff's Reply in Support of Motion for Preliminary Injunction ("Endo Br."), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936, Doc. 23 at 20 (D.D.C. Dec.14, 2012).

[49] Defendants' Response to the Court's November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936, Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

[50] *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl.) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936 ,Doc. 18-4(D.D.C. Dec. 9, 2012).

184. In its Citizen Petition, Endo asserted that redesigned Opana ER had "safety advantages." However, in rejecting the Petition in a 2013 decision, the FDA found that study data "show that [the reformulated version's] extended-release features can be compromised when subjected to ... cutting, grinding, or chewing." The FDA also determined that "reformulated Opana ER" could also be "readily prepared for injection and more easily be prepared for injection[.]" In fact, the FDA warned that preliminary data—including in Endo's own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

185. Over time, evidence continued to mount that injection was becoming the preferred means of abusing Opana ER, making Opana ER *less safe* than the original formulation. Injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.[51] In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500%.

186. Nevertheless, Endo continued to market the drug as tamper-resistant and abuse-deterrent, including, upon information and belief, to doctors in Stark County. In addition, Endo sales representatives did not disclose evidence that Opana was easier to abuse intravenously, including, upon information and belief, in Stark County. Indeed, a review of nationally-collected surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that

[51] The CDC does not know why the redesigned Opana ER causes TTP, but it notes it did not appear in other prescription opioids prepared for injection. "Thrombotic Thrombocytopenic Purpura (TTP)–Like Illness Associated with Intravenous Opana ER Abuse — Tennessee, 2012," *Morbidity and Mortality Weekly Report* (Jan. 11, 2013). The CDC suggested it could be linked to inactive ingredients that make the product more difficult to crush or grind. No reports of Opana ER and TTP occurred prior to the reformulation.

prescribers remember being told Opana ER was tamper resistant, even after the May 2013 denial of Endo's Citizen Petition. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential."

187. In its written materials, Endo marketed Opana ER as having been ***designed*** to be crush resistant, knowing that this would (falsely) imply that Opana ER actually ***was*** crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced "the completion of the company's transition of its OPANA ER franchise to the new formulation designed to be crush resistant."[52] The press release further stated that: "We firmly believe that the new formulation of OPANA ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers."[53] In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."[54]

188. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant."

189. In a 2016 settlement with Endo, the New York Attorney General found that statements that Opana ER was "designed to be, or is crush resistant" were false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The New

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[52] Ex. E to Rurka Decl., *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 12-v-1936, Doc. 18-2 at 1 (D.D.C. Dec. 9, 2012).

[53] *Id.*

[54] Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl.) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*., No. 1:12-cv-01936,Doc. 18-4 (D.D.C. Dec. 9, 2012).

York Attorney General also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to insurers and pharmacy benefit managers, which also would have impacted the availability of Opana ER in Stark County.

3. Mallinckrodt's Deceptive Marketing of Exalgo and Xartemis XR

190. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt's promotional materials stated that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving."[55] One member of the FDA's Controlled Substance Staff, however, noted in 2010 that hydromorphone has "a high abuse potential comparable to oxycodone" and further stated that "we predict that Exalgo will have high levels of abuse and diversion."[56]

191. In addition, with respect to Xartemis XR, Mallinckrodt's promotional materials stated that "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."[57] In anticipation of Xartemis XR's approval, Mallinckrodt added 150-200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate "hundreds of millions in revenue."[58]

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[55] Mallinckrodt Press Release, *FDA Approves Mallinckrodt's EXALGO® (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe Chronic Pain* (Aug. 27, 2012), available at http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159

[56] http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/anestheticandanalgesicdrugproductsadvisorycommittee/ucm187490.pdf at 157-58.

[57] Mallinckrodt, *Responsible Use of Opioid Pain Medications* (Mar. 7, 2014) at 14.

[58] Samantha Liss, *Mallinckrodt banks on new painkillers for sales*, St. Louis Business Journal (Dec. 30, 2013), available at http://argentcapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/

G. INSYS EMPLOYED FRAUDULENT, ILLEGAL, AND MISLEADING MARKETING SCHEMES TO PROMOTE SUBSYS

186. Insys' opioid, Subsys, was approved by the FDA in 2012 for "management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." Under FDA rules, Insys could only market Subsys for this use. Subsys consists of the highly addictive narcotic, fentanyl, administered via a sublingual (under the tongue) spray, which provides rapid-onset pain relief. It is in the class of drugs described as Transmucosal Immediate-Release Fentanyl ("TIRF").

187. To reduce the risk of abuse, misuse, and diversion, the FDA instituted a Risk Evaluation and Mitigation Strategy ("REMS") for Subsys and other TIRF products, such as Teva's Actiq and Fentora. The purpose of REMS was to educate "prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose" for this type of drug and to "ensure safe use and access to these drugs for patients who need them."[59] Prescribers must enroll in TIRF REMS before writing a prescription for Subsys.

188. Since its launch, Subsys has been an extremely expensive medication, and Insys has increased its prices every year. Depending on a patient's dosage and frequency of use, a month's supply of Subsys could cost in the thousands of dollars.

189. Due to its high cost, in most instances prescribers must submit Subsys prescriptions to insurance companies or health benefit payors for prior authorization to determine whether they will pay for the drug prior to the patient attempting to fill the prescription. According to the U.S. Senate Homeland Security and Governmental Affairs Committee Minority Staff Report ("Staff Report"), the prior authorization process includes "confirmation that the patient had an active

[59] Press Release, FDA, FDA Approves Shared System REMS for TIRF Products, December 29, 2011.

cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate. If any one of these factors was not present, the prior authorization would be denied . . . meaning no reimbursement would be due."[60]

190. These prior authorization requirements proved to be daunting. Subsys received reimbursement approval in only approximately 30% of submitted claims. In order to increase approvals, Insys created a prior authorization unit, called the Insys Reimbursement Center (IRC) to obtain approval for Subsys reimbursements. This unit employed a number of fraudulent and misleading tactics to secure reimbursements, including falsifying medical histories of patients, falsely claiming that patients had cancer, and providing misleading information to insurers and payors regarding patients' diagnoses and medical conditions.

191. Subsys, has proved to be extremely profitable for Insys. Insys made approximately $330 million in net revenue from Subsys last year. Between 2013 and 2016, the value of Insys stock rose 296%.

192. Since its launch in 2012, Insys has aggressively worked to grow its profits through fraudulent, illegal, and misleading tactics. Through its sales representatives and other marketing efforts, Insys deceptively promoted Subsys as safe and appropriate for uses such as neck and back pain, without disclosing the lack of approval or evidence for such uses, and misrepresented the appropriateness of Subsys for treatment those conditions. It implemented a kickback scheme wherein it paid prescribers for fake speakers programs in exchange for prescribing Subsys. And it defrauded insurance providers and health benefit payors into paying for improper prescriptions

[60] Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization.*

of Subsys. These fraudulent and misleading schemes had the effect of pushing Insys' highly potent and dangerous opioid onto patients who did not need it, further exacerbating the opioid epidemic.

193. In addition, Insys incentivized its sales force to engage in illegal and fraudulent conduct. Many of the Insys sales representatives were new to the pharmaceutical industry and their base salaries were low compared to industry standard. The compensation structure was heavily weighed on commissions, and rewarded reps more for selling higher (and more expensive) doses of Subsys, a "highly unusual" practice because most companies consider dosing a patient-specific decision that should be made by a doctor.[61]

194. The Insys "speakers program" was perhaps its most widespread and damaging scheme. According to a report by the Southern Investigative Reporting Foundation ("SIRF") a former Insys salesman, Ray Furchak, alleged in a *qui tam* action that the sole purpose of the speakers program was "in the words of his then supervisor Alec Burlakoff, 'to get money in the doctor's pocket.'" Furchak went on to explain that "[t]he catch . . . was that doctors who increased the level of Subsys prescriptions, and at higher dosages (such as 400 or 800 micrograms instead of 200 micrograms), would receive the invitations to the program—and the checks."[62]

195. Insys' sham speaker program and other fraudulent and illegal tactics have been outlined in great detail in indictments and guilty pleas of Insys executives, employees, and prescribers across the country, as well as in a number of lawsuits against the company itself.

196. In May of 2015, two Alabama pain specialists were arrested and charged with illegal prescription drug distribution, among other charges. The doctors were the top prescribers

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[61] Katie Thomas, *Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller, New York Times,* May 13, 2014.

[62] Roddy Boyd, *Insys Therapeutics and the New 'Killing It'"*, Southern Investigative Reporting Foundation, The Investigator, April 24, 2015.

of Subsys, though neither were oncologists. According to prosecutors, the doctors received illegal kickbacks from Insys for prescribing Subsys. Both doctors had prescribed Subsys to treat neck, back, and joint pain. In May of 2017, one of the doctors was sentenced to 20 years in prison.

197. In June of 2015, a nurse practitioner in Connecticut described as the state's highest Medicare prescriber of narcotics, plead guilty to receiving $83,000 in kickbacks from Insys for prescribing Subsys. Most of her patients were prescribed the drug for chronic pain. Insys paid the nurse as a speaker for more than 70 dinner programs at a rate of approximately $1,000 per event; however, she did not give any presentations. In her guilty plea, the nurse admitted that she was receiving the speaker fees in exchange for writing prescriptions for Subsys.

198. In August of 2015, Insys settled a complaint brought by the Oregon Attorney General, alleging that Insys paid doctors "speaking fees" to increase prescriptions of Subsys, among other allegations. In its complaint, the Oregon Department of Justice cited Insys for, among other things, misrepresenting to doctors that Subsys could be used to treat migraine, neck pain, back pain, and other uses for which Subsys is neither safe nor effective, and employing an unconscionable scheme, including "speaking fees," whereby payments that were intended to be kickbacks were made to doctors to incentivize the doctor to prescribe Subsys. [63]

199. In February of 2016, a former Insys sales manager pled guilty to conspiracy to commit health care fraud, including engaging in a kickback scheme in order to induce one of the Alabama prescribers discussed above to prescribe Subsys. The plea agreement states that nearly all of the Subsys prescriptions written by the doctor were off-label to non-cancer patients.

200. In August of 2016 the State of Illinois sued Insys for its deceptive and illegal

[63] In The Matter of Insys Therapeutics, Inc., Notice of Unlawful Trade Practices and Proposed Resolution, July 10, 2015.

practices. The complaint alleged that Insys marketed Subsys to high-volume prescribers of opioid drugs instead of to oncologists whose patients experienced the breakthrough cancer pain for which the drug is indicated. The complaint explains that Insys categorized prescribers into deciles (D1-D10) according to the number of rapid onset opioids (ROOs) prescribed. The sales reps were instructed to call on the highest volume ROO prescribers more frequently than the low volume ROO prescribers, and encouraged to obtain the majority of their sales from one or two high volume prescribers.

201. The Illinois complaint also details how Insys used its speaker program to pay high volume prescribers to prescribe Subsys. The speaker events took place at upscale restaurants in the Chicago area, and Illinois speakers received a speaker "honorarium" ranging from $700 – $5,100 in addition to their meal. The prescribers were allowed to order as much food and alcohol as they wanted. At most of the events, the "speaker" being paid by Insys did not speak, and, on many occasions, the only attendees at the events were the "speaker" and an Insys sales rep.

202. Stark County prescribers participated in the "speaker" programs as well. According to publicly reported data, a Stark County pain medicine doctor received $57,767.44 from Insys beginning the third quarter of 2013 and ending in 2016. The majority of these payments were for promotional speaking. Another Stark County pain medicine doctor received $23,682 during this time frame, with the majority of the payments also being related to public speaking. The payments to these two doctors accounted for $81,450.04 of the $85,007.21 that Insys paid to County prescribers during this time.

203. In December of 2016, six Insys executives and managers were indicted. The indictment alleged that the former Insys employees conspired to bribe prescribers, many of whom operated pain clinics, in order to induce them to prescribe Subsys. In exchange for bribes and

kickbacks, the indictment states, the prescribers wrote large numbers of prescriptions for the patients, though most of them were not diagnosed with cancer. In announcing the indictments, the Special Agent in charge of the Boston Division of the FBI noted that this scheme "contributed to the growing opioid epidemic and placed profit before patient safety."[64]

204. Insys' misleading marketing of Subsys as appropriate for non-cancer pain occurred in Stark County. Publicly available data shows that between the third quarter of 2013 and 2016 Insys sales representatives visited County providers approximately 608 times, and, as described above, spent $85,007.21. The majority of these visits were to doctors were prescribers who practiced in pain medicine. In addition, upon information and belief, Insys employed its fraudulent prior authorization scheme to seek approval of Stark County doctors' prescriptions of Subsys.

H. PURDUE MISREPRESENTED AND DEFENDANTS HID THEIR LACK OF COOPERATION WITH LAW ENFORCEMENT.

205. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."[65]

206. As described in Section B.1, Purdue's public stance long has been that "bad apple" patients and drug diversion to illicit secondary channels—and not widespread prescribing of OxyContin and other opioids for chronic pain—are to blame for widespread addiction and abuse.

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[64] *Press Release, United States Attorney's Office District of Massachusetts, Pharmaceutical Executives Charged in Racketeering Scheme, December 8, 2016.*

[65] Purdue, *Setting The Record Straight On OxyContin's FDA-Approved Label*, May 5, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

To address the problems of illicit use and diversion, Purdue promotes its funding of various drug abuse and diversion prevention programs and introduction of ADF opioids. This allows Purdue to present itself as a responsible corporate citizen while continuing to profit from the commonplace prescribing of its drugs, even at high doses for long-term use.

207. At the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue's recent pronouncements in response to the opioid abuse.

208. Touting the benefits of ADF opioids, Purdue's website asserts: "[W]e are acutely aware of the public health risks these powerful medications create . . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . ."[66] Purdue's statement on "Opioids & Corporate Responsibility" likewise states that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government agencies."[67] And, responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."[68]

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[66] Purdue website, *Opioids With Abuse-Deterrent Properties*, available at http://www.purduepharma. com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/.

[67] Purdue website, *Opioids Corporate Responsibility*, available at http://www.purduepharma.com/ news-media/opioids-corporate-responsibility/.

[68] Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/. Contrary to its public statements, Purdue seems to have worked

209. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

210. Yet, Purdue, which possessed detailed information that it could use to identify suspicious prescribers and likely diversion, failed to report this activity to law enforcement. Instead, it used the data for marketing purposes. Purdue's failure to report suspicious activity was the subject of detailed reporting by the *Los Angeles Times*, which relied, in part, on internal Purdue documents and interviews with former employees and law enforcement. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids, whom it described as "Region Zero." Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or "80s," as they were known on the street, were a prime target for diversion). Health care providers added to the database no longer were detailed, and sales representatives received no compensation tied to these providers' prescriptions.

211. Meanwhile, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. Purdue's former senior compliance officer acknowledged in an interview with the *Los Angeles Times* that in five years of

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behind the scenes to push back against law enforcement.

investigating suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

212. The same was true of prescribers. For example, despite Purdue's knowledge of illicit prescribing from one Los Angeles clinic which its district manager called an "organized drug ring," Purdue did not report its suspicions from 2009 until 2013—long after law enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

213. Upon information and belief, Purdue would have had information about suspicious prescribers through multiple sources. Specifically, upon information and belief, sales representatives would have the opportunity to observe suspicious activity and would become familiar with the territories they covered. In addition, Purdue reportedly obtained detailed information about individual doctors' prescribing habits obtained through a contract with a company called I.M.S., now known as IQVIA Holdings, Inc. Finally, upon information and belief, manufacturers engaged in the practice of paying rebates and/or chargebacks to wholesalers for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts, but which information would also have signaled red flags of likely diversion.[69]

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[69] *The Washington Post* has described the practice as industry-wide, and a trade organization of which Defendants are members, the Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")), includes a "Contracts and Chargebacks Working Group," suggesting a standard practice. Further, at least one manufacturer, Mallinckrodt, has acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors)" and promised that from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion." Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC at 5 (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download. ("2017 Mallinckrodt MOA").

214. Purdue would have understood that its failure to report, and refrain from fueling, suspected diversion had an impact. Purdue was not entitled to be a passive (but profitable) observer of suspicious activity. It had a responsibility both to exercise due care under the circumstances, and to comply with the voluntary obligations it assumed through its public statements. In addition, Purdue has statutory and regulatory obligations, as a manufacturer of controlled substances, to monitor and report suspicious conduct in the sale and distribution of controlled substances. *See infra* Section I. This enforcement regime recognizes that drug companies often have more, and more timely, information on the distribution of their drugs that law enforcement authorities.

215. The New York Attorney General found that Purdue placed 103 New York health care providers on its No-Call List between January 1, 2008 and March 7, 2015, and that Purdue's sales representatives had detailed approximately two-thirds of these providers, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period . . . ."[70]

216. Similarly, the New York Attorney General similarly found that Endo knew, as early as 2011, that Opana ER was being abused in New York, but certain sales representatives who detailed New York health care providers testified that they did not know about any policy or duty to report problematic conduct. The New York Attorney General further determined that Endo detailed health care providers who were subsequently arrested or convicted for illegal prescribing

[70] Attorney General of the State of New York, *In the Matter of Purdue Pharma L.P.*, Assurance No.: 15-151, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 5.

of opioids a total of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER).[71]

217. Along the same lines, Mallinckrodt claims to be "committed . . . to fighting opioid misuse and abuse," and further asserts that: "In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances, ..."

I. DEFENDANTS DELIBERATELY DISREGARDED THEIR DUTIES TO REPORT AND TERMINATE SUSPICIOUS ORDERS AND TO CEASE SUPPLYING SUSPICIOUS PRESCRIBERS.

218. By the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. This created both a vastly and dangerously larger market for opioids in Stark County and another lucrative opportunity for Defendants, who compounded this harm by failing to maintain effective controls against diversion and instead facilitating the supply of far more opioids than could have been justified to serve the market, and supplying opioids they knew or should have known were being abused or diverted. Defendants' failure to investigate, report, and terminate orders, and to report and cease supplying prescribers, that they knew or should have known were suspicious breached both their statutory and common law duties.

219. First, under the common law, the Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, Defendants breached their duty

[71] Attorney General of the State of New York, *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No.: 15-228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 10-12, *available at* https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

to exercise reasonable care as manufacturers of narcotic substances and both created and failed to prevent a foreseeable risk of harm to the Plaintiffs. As the supply of opioids and the evidence of addiction to and abuse of these drugs grew, Defendants were again reminded of both the nature and harms of opioid exposure and use.

220. Second, each Defendant assumed a duty, when speaking publically about opioids and their efforts and commitment regarding diversion of prescription opioids, to speak accurately and truthfully.

221. Third, Defendants violated their statutory obligations under Ohio law, which also incorporates the federal Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq.* and its implementing regulations. *See* O.A.C. §§ 4729-9-16(L) and 4729-9-28(I) (mandating that "[w]holesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations"). Similarly, under Ohio law, manufacturers, as a condition of their licensure, must demonstrate that "[a]dequate safeguards are assured to prevent the sale of dangerous drugs other than in accordance with section 4729.51 of the Revised Code. R.C. § 4729.53. The Ohio Administrative Code imposes obligations and duties upon "licensees" and "registrants," including manufacturers, to "provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs." O.A.C. 4729-9-05(A).

222. Each of the Defendants was required to register with the DEA to manufacture and/or distribute Schedule II controlled substances. *See* 21 U.S.C. § 823(a)-(b), (e); 28 C.F.R. § 0.100. Federal regulations issued under the CSA and incorporated into Ohio law pursuant to O.A.C.§§ 4729-9-16(L) and 4729-9-28(I) further mandate that, as registrants, manufacturers and distributors alike, "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74(b).

223. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970. The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market." Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain. All registrants – which includes all manufacturers and distributors of controlled substances -- must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

224. The CSA requires manufacturers and distributors of Schedule II substances alike opioids to: (a) limit sales within a quota set by the DEA for the overall production of Schedule II substances like opioids; (b) register to manufacture or distribute opioids; (c) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; and (d) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

225. To ensure the integrity of the closed system, federal regulations issued under the CSA mandate that all registrants, manufacturers and distributors alike, "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. §

1301.74(b). Registrants are not entitled to be passive (but profitable) observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id.* Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id.* Other red flags may include, for example, "[o]rdering the same controlled substance from multiple distributors."

226. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a distributor or manufacturer need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

227. Any of the red flags identified by law trigger a duty to report; however, this list is not exclusive. Other factors—such as whether the order is skewed toward high dose pills, or orders that are skewed towards drugs valued for abuse, rather than other high-volume drugs, such as cholesterol medicines, also should alert distributors to potential problems. Distributors also have a duty to know their customers and the communities they serve. To the extent that, through this process of customer due diligence, a distributor observes suspicious circumstances—such as cash transactions or young and seemingly healthy patients filling prescriptions for opioids at a pharmacy they supply– can trigger reasonable suspicion. A single order can warrant scrutiny, or it may be a

pattern of orders, or an order that is unusual given the customer's history or its comparison to other customers in the area.

228. In sum, Defendants, due to the position of special trust and responsibility afforded them by their status as registrants in the distribution chain of controlled substances, have several responsibilities with respect to suspicious orders of opioids. First, they must set up a system designed to detect such orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All flagged orders must be reported to relevant enforcement authorities.[72] Further, they must also stop shipment of any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.[73]

229. These statutes and regulations reflect a standard of conduct and care below which reasonably prudent manufacturers would not fall. Together, these laws set standards of care that make clear that wholesalers and manufacturers of controlled substances alike possess, and are expected to possess, specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the distribution chain is not properly controlled.

230. Further, these laws set standards of care that make clear that Defendants have a duty and responsibility to exercise their specialized and sophisticated knowledge, information,

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[72] *Id.*

[73] *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007) (applying federal requirements no less stringent than those of Ohio); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017) (same).

skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

231. Defendants were well aware they had an important role to play in the controlled system of prescription opioid distribution, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

232. The DEA, for example, sent a letter to distributors and manufacturers alike on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[74] The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."

233. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[75]

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[74] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8 (hereinafter "2007 Rannazzisi Letter").

[75] *See* 2017 Mallinckrodt MOA.

234. In the press release accompanying the settlement, the Department of Justice stated: "Mallinckrodt did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . . Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . ."[76]

235. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[77]

236. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

> With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:

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[76] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

[77] *Id.*

i. conduct adequate due diligence of its customers

ii. detect and report to the DEA orders of unusual size and frequency;

iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:

1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,

2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and

3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;

iv. use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[78]

237. In connection with that settlement, Mallinckrodt admitted that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[79] Mallinckrodt further stated that it "recognizes the importance of the prevention of

[78] 2017 Mallinckrodt MOA at 2-3.

[79] *Id.* at 1.

diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 C.F.R. 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product."[80] Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[81]

238. Mallinckrodt also acknowledged that at certain times prior to January 1, 2012, "certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards outlined in letter from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007."[82]

239. In connection with the investigation of Mallinckrodt, the Department of Justice and DEA determined that Mallinckrodt ignored its responsibility to report suspicious orders of as many as 500 million of its pills that were sent to Florida from 2008 and 2012, which was 66% of all oxycodone sold in the state. Mallinckrodt, through its internal sources, knew that opioids it was supplying were being used to fill suspicious orders in Florida, and knew or should have known that those opioids were being diverted into Ohio communities. In light of a crack-down on in-state pill by Ohio authorities, as well as Ohio's implementation of a Prescription Drug Monitoring Program, traffickers in Ohio routed orders through Florida pharmacies or prescribers for diversion back into Ohio communities on a route that became known as the "Florida Pipeline" or "OxyContin Express."[83] Moreover, Mallinckrodt recognized in November 2010 that 68% of the

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[80] *Id.* at 4.

[81] *Id.*

[82] *Id.* at 3-4.

[83] Decl. of DEA Diversion Investigator Christopher Kresnak, *KeySource Medical Inc. v. Holder*, No. 1:11-cv-00393, Doc. 9-2 ¶ 3 (S.D. Ohio June 30, 2011).

purchases by one of its distributors, Cincinnati-based KeySource Medical, Inc., were for prescription opioids, and that 91% of this customer's purchasers were sent to Florida.[84]

240. Mallinckrodt also had other information that would have alerted it to potential diversion. Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants." As part of the settlement, Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[85]

241. Upon information and belief, the other Defendants also had access to chargeback data and information that would have presented red flags of potential diversion of the drugs they supplied. *The Washington Post* has described the practice of collecting chargeback data as industry-wide. Further, the Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")), a trade association of pharmaceutical distributors, which also actively recruits manufacturer members, includes a "Contracts and Chargebacks Working Group," suggesting a standard practice. Although the entire HDA membership directory is private, the HDA website confirms that Defendants Purdue, Endo, Mallinckrodt and Cephalon were members of the HDA, and the HDA's website indicates that Janssen would have been represented through Johnson & Johnson Health Care Systems Inc.

242. Upon information and belief, at all relevant times, the Defendants were in possession of national, regional, state, and local prescriber- and patient-level data that allowed

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[84] United States' Opposition to Plaintiff's Motion for a Preliminary Injunction, *KeySource Medical Inc. v. Holder*, No. 1:11-cv-00393, Doc. 9 at 6 (S.D. Ohio June 30, 2011).

[85] 2017 Mallinckrodt MOA at 5.

them to track prescribing patterns over time. Purdue obtained detailed data about individual doctors' prescribing patterns from I.M.S., which it used to target its marketing. Moreover, as a routine practice, "[p]harmaceutical companies monitor the return on investment of detailing - and all promotional efforts - by prescription tracking."[86] Companies such as IMS Health, Dendrite, Verispan, and Wolters Kluwer, referred to as "information distribution companies," "health information organizations" or "data vendors" purchase prescription records from pharmacies, the majority of which sell these records.[87] The largest such company, IMS Health, has been described as procuring records on about 70% of prescriptions filled in community pharmacies.[88] Pharmaceutical companies are the primary customers for the prescribing data sold by these vendors.[89]

243. The same information, which is often used to identify "high prescribers" for purposes of marketing efforts, would have allowed Defendants to identify pill mills and red flags of abuse or diversion. In fact, one of the data vendor's experts previously testified that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product."[90]

244. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view, but is in the possession of Defendants.

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[86] Joint Appendix, *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at *388-89 (Feb. 22, 2011) (Fugh-Berman A, Ahari S (2007) Following the Script: How Drug Reps Make Friends and Influence Doctors. PLoS Med 4(4): e150. doi:10.1371/journal.pmed.0040150).

[87] *Id.* at 389.

[88] *Id.*

[89] *Id.*

[90] *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 705207, *467-471 (Feb. 22, 2011); *see also* Joint Appendix, *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at *204 (Feb. 22, 2011).

245. Yet, publically available information confirms that Defendants would have been alerted to potentially suspicious prescribers or orders of opioids in and affecting Plaintiffs' communities.

246. All told, Stark County, with an average population from 2010 to 2017 of approximately 375,000, received a total of 203,604,737 retail doses of opioid analgesics, with a high of 27,679,927 in 2013. This amounted to 135 doses per opioid patient.

247. Given this, and the additional red flags described below, Defendants would, upon information and belief, have been aware of suspicious orders and prescribers. The Plaintiffs' information and belief rests upon the following facts:

(a) manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

(b) manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies; and

(c) manufacturers regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion.

248. As discussed above, the volume of opioids distributed in Stark County is so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses. This is particularly true given that Stark County's supply of opioids even exceeded statewide figures—an already high baseline given Ohio's unfortunate placement at the epicenter of the opioid crisis.

249. Further, as recently as February 2018, a Stark County doctor was indicted on more than 270 charges of running a pill mill after two people died of drug overdoses from drugs obtained in his practice. The doctor, who worked at a family practice, was charged with involuntary manslaughter, Medicaid fraud, drug trafficking, grand theft, and other offenses. Upon information

and belief, this prescriber, and the pharmacies at which the providers' patients filled prescriptions for opioids, yielded orders of unusual size, frequency, or deviation, or raised other warning signs that should have alerted Defendants not only to an overall oversupply in Stark County, but specific instances of diversion. In Ohio, physicians or clinics engaged in illicit prescribing have been found to frequently team with particular pharmacies to distribute prescription opioids.

250. In addition, the crisis of fatal overdoses from prescription opioids in Ohio communities has been widely publicized for years. Stark County, is unfortunately, among the communities hardest hit by the opioid epidemic. The Plaintiffs have seen a dramatic rise in fatal drug overdoses. Many of these deaths are attributable to prescription opioids, and increasingly, to illicit opiates, to which people who have become addicted to prescription opioids often transition. The CDC estimates that for every opioid-related death, there are 733 non-medical users. Manufacturing Defendant thus had every reason to believe that illegal diversion was occurring in Stark County.

251. Not only were prescription opioids diverted within Stark County, upon information and belief, they were being diverted into Stark County from pill mills further south in Ohio, that, upon information and belief, Defendants also failed to report or cease supplying. An epidemiological report from the Ohio Governor's Cabinet opiate action team cited the shutdown of southern Ohio pill mills as one of the chief factors in an increase throughout Ohio in heroin overdose rates (which, as explained below, is the drug turned to by prescription opioid users when those drugs are no longer available or too expensive). Consistent with the observed statewide trend, Stark County has seen a spike in heroin overdoses and lives lost to synthetic opiates, such as fentanyl.

252. In addition, upon information and belief, the Defendants would have known that Ohio's crack-down on pill mills within the state did not prevent suspicious orders from being placed in the state and ultimately diverted to illicit use in Ohio communities. For example, as discussed above, Mallinckrodt found in November 2010 that 68% of the purchases by one of its distributors, Cincinnati-based KeySource Medical, Inc., were for prescription opioids, and that 91% of this customer's purchasers were sent to Florida.[91] During that time, Florida lacked a prescription drug monitoring program similar to Ohio, and traffickers would recruited others to travel to Florida to pick up the drugs Mallinckrodt, through wholesale distributors a, had shipped there, and bring them back to Ohio, a route that became known as the "Florida Pipeline" or "OxyContin Express."[92] According to the *Washington Post*, an internal summary of a federal case against Mallinckrodt, described above, showed that "Mallinckrodt's response was that 'everyone knew what was going on in Florida but they had no duty to report it.' "[93]

253. Upon information and belief, Defendants would have been aware that as Ohio cracked down on opioid suppliers, out-of-state suppliers filled the gaps, directly impacting Plaintiffs' communities. As described above, Florida in particular assumed a prominent role, as its lack of regulatory oversight created a fertile ground for pill mills. Residents of other states would simply drive to Florida, stock up on pills from a pill mill, and transport them back to home

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[91] United States' Opposition to Plaintiff's Motion for a Preliminary Injunction, *KeySource Medical Inc. v. Holder*, No. 1:11-cv-00393, Doc. 9 at 6 (S.D. Ohio June 30, 2011).

[92] Decl. of DEA Diversion Investigator Christopher Kresnak, *KeySource Medical Inc. v. Holder*, No. 1:11-cv-00393, Doc. 9-2 ¶ 3 (S.D. Ohio June 30, 2011).

[93] The Government's Struggle to Hold Opioid Manufacturers Accountable: Sixty-six percent of all oxycodone sold in Florida came from this company. But the DEA's case against it faltered, *Washington Post*, (Apr. 2, 2017), https://www.washingtonpost.com/graphics/investigations/deamallinckrodt/?utm_term=.256b39de1578

to sell. The practice became so common that authorities dubbed these individuals "prescription tourists."

254. The facts surrounding numerous criminal prosecutions illustrate the common practice. For example, one man from Warren County, Ohio, sentenced to four years for transporting prescription opioids from Florida to Ohio, explained that he could get a prescription for 180 pills from a quick appointment in West Palm Beach, and that back home, people were willing to pay as much as $100 a pill—ten times the pharmacy price. In Columbus, Ohio, a DEA investigation led to the 2011 prosecution of sixteen individuals involved in the "oxycodone pipeline between Ohio and Florida."[94] When officers searched the Ohio home of the alleged leader of the group, they found thousands of prescriptions pills, including oxycodone and hydrocodone, and $80,000 in cash. In 2015, another Columbus man was sentenced for the same conduct—paying couriers to travel to Florida and bring back thousands of prescription opioids, and, in the words of U.S. district judge Michael Watson, contributing to a "pipeline of death."[95]

255. Outside of Atlanta, Georgia, four individuals pled guilty in 2015 for operating a pill mill; the U.S. attorney's office found that most of the pain clinic's customers came from other states, including Ohio. Another investigation in Atlanta led to the 2017 conviction of two pharmacists who dispensed opioids to customers of a pill mill across from the pharmacy; many of those customers were from other states, including Ohio.

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[94] *16 charged in 'pill mill' pipeline*, Columbus Dispatch (June 7, 2011), http://www.dispatch.com/content/stories/local/2011/06/07/16-charged-in-pill-mill-pipeline.html.

[95] *Leader of Ohio pill-mill trafficking scheme sentenced*, Star Beacon (July 16, 2015), http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html.

256. In yet another case, defendants who operated a pill mill in south Florida were tried in eastern Kentucky based on evidence that large numbers of customers transported oxycodone back to the area for both use and distribution by local drug trafficking organizations. As explained by the Sixth Circuit in its decision upholding the venue decision, "[d]uring its existence, the clinic generated over $10 million in profits. To earn this sum required more business than the local market alone could provide. Indeed, only about half of the PCB's customers came from Florida. Instead, the clinic grew prosperous on a flow of out-of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft. Lauderdale, including from Ohio."[96]

257. The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so well traveled that it became known as the Blue Highway, a reference to the color of the 30mg oxycodone pills manufactured by Mallinckrodt. Eventually, as police began to stop vehicles with certain out-of-state tags cruising north on I-75, the prescription tourists adapted. They rented cars just over the Georgia state line to avoid the telltale out-of-state tag. If they were visiting multiple pill mills on one trip, they would stop at FedEx between clinics to mail the pills home and avoid the risk of being caught with multiple prescriptions if pulled over.

258. Further, the Plaintiffs form part of the Ohio High Intensity Drug Trafficking Area ("HIDTA") designated by the U.S. Department of Justice National Drug Intelligence Center ("NDIC"). This designating requires, among other things, that an area be a "significant center of illegal drug production, manufacturing, importation, or distribution," that "State, local, and tribal law enforcement agencies have committed resources to respond to the drug trafficking problem in the area, thereby indicating a determination to respond aggressively to the problem," and that

[96] *United States v. Elliott*, 876 F.3d 855, 858 (6th Cir. 2017).

"Drug-related activities in the area are having a significant harmful impact in the area and in other areas of the country."

259. In 2011, the NIDC described the overall drug threat in the Ohio HIDTA as increased, "particularly from increased trafficking and abuse of heroin and prescription opioids." The report specifically recognized that, "prescription opioid diversion and abuse are increasing, resulting in a significant overall threat from prescription and illicit opioid abuse within the HIDTA region." Moreover, the "already high" availability of diverted prescription opioids was increasing.

260. Based upon all of these red flags, it can be fairly inferred that Defendants had information about suspicious orders that they did not report, and also failed to exercise due diligence before filling orders from which drugs were diverted into illicit uses in Plaintiffs' communities.

J. BY INCREASING OPIOID PRESCRIPTIONS AND USE, DEFENDANTS COLLECTIVELY FUELED THE OPIOID EPIDEMIC AND SIGNIFICANTLY HARMED PLAINTIFFS AND THEIR RESIDENTS.

261. Defendants' misrepresentations prompted Stark County health care providers to prescribe and patients to take opioids for the treatment of chronic pain. Through their marketing, Defendants overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks and benefits of long-term opioid use. Further, Purdue, and upon information and belief, other Defendants compounded these harms by turning a blind eye to red flags of illicit prescribing or diversion. The foreseeable result has been a public health epidemic that is devastating Plaintiffs and their residents.

262. Defendants' deceptive marketing substantially contributed to an explosion in the use of opioids across the country. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most

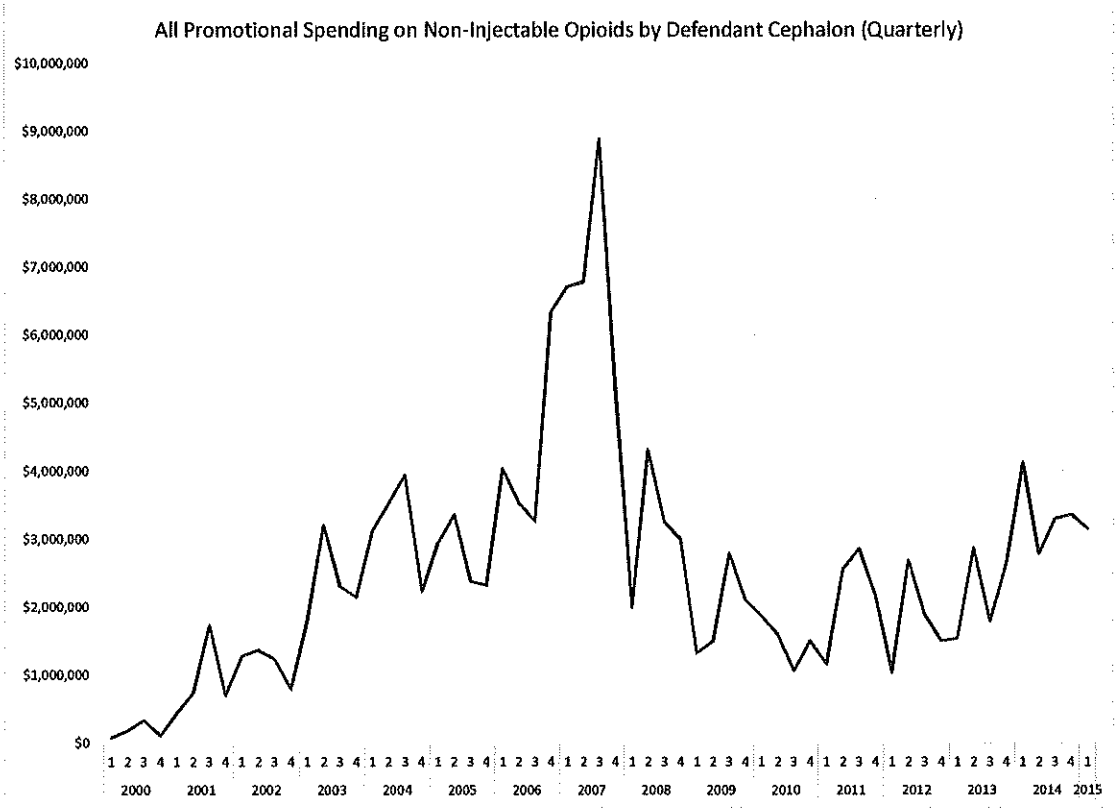
common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

263. Often, the use of opioids begins with acute pain – in sports, on the job, at the dentist, or in a car accident – for which the patient is prescribed opioids. The false sense of security created by Marketing Defendants' deceptive messages concerning the risks and benefits of opioids, especially the risk of addiction, would also make doctors and patients feel more comfortable in continuing to use opioids for lingering pain needs or demands, causing some patients to become dependent and addicted.

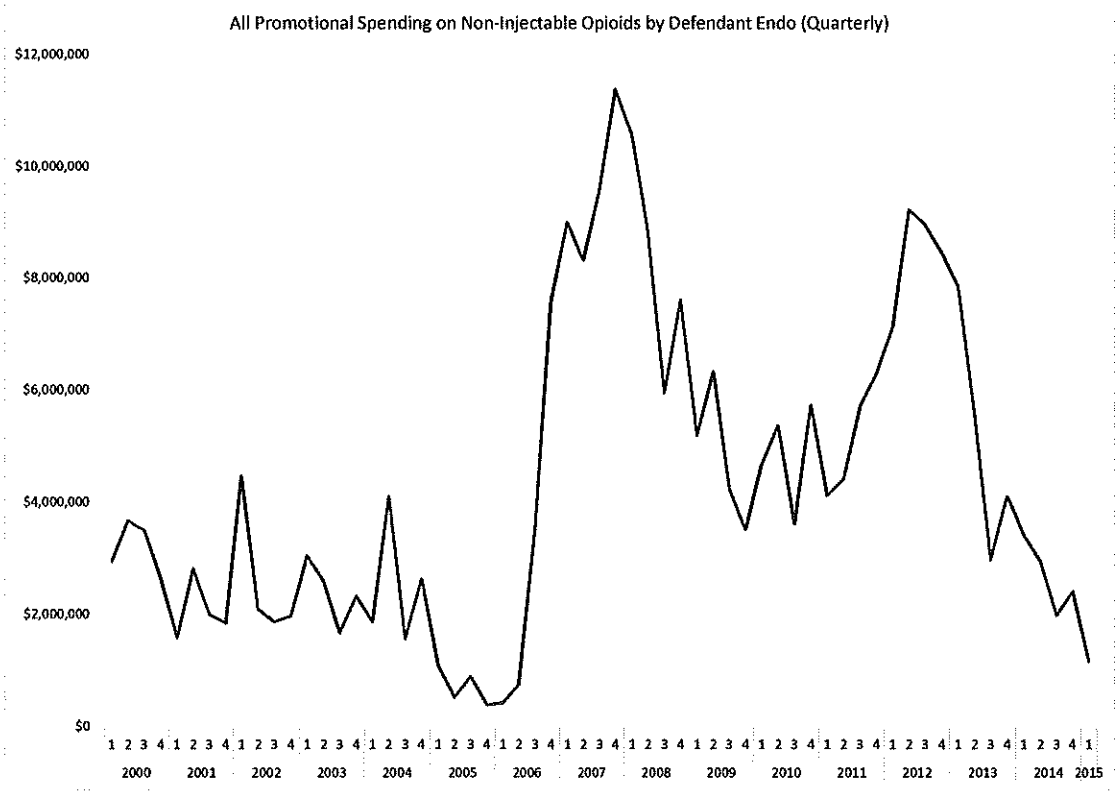
264. Upon information and belief, overall sales of opioids in Ohio have skyrocketed, and Stark County is no exception.

265. Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Defendants spent $166 million on detailing branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Teva, and $10 million by Endo.

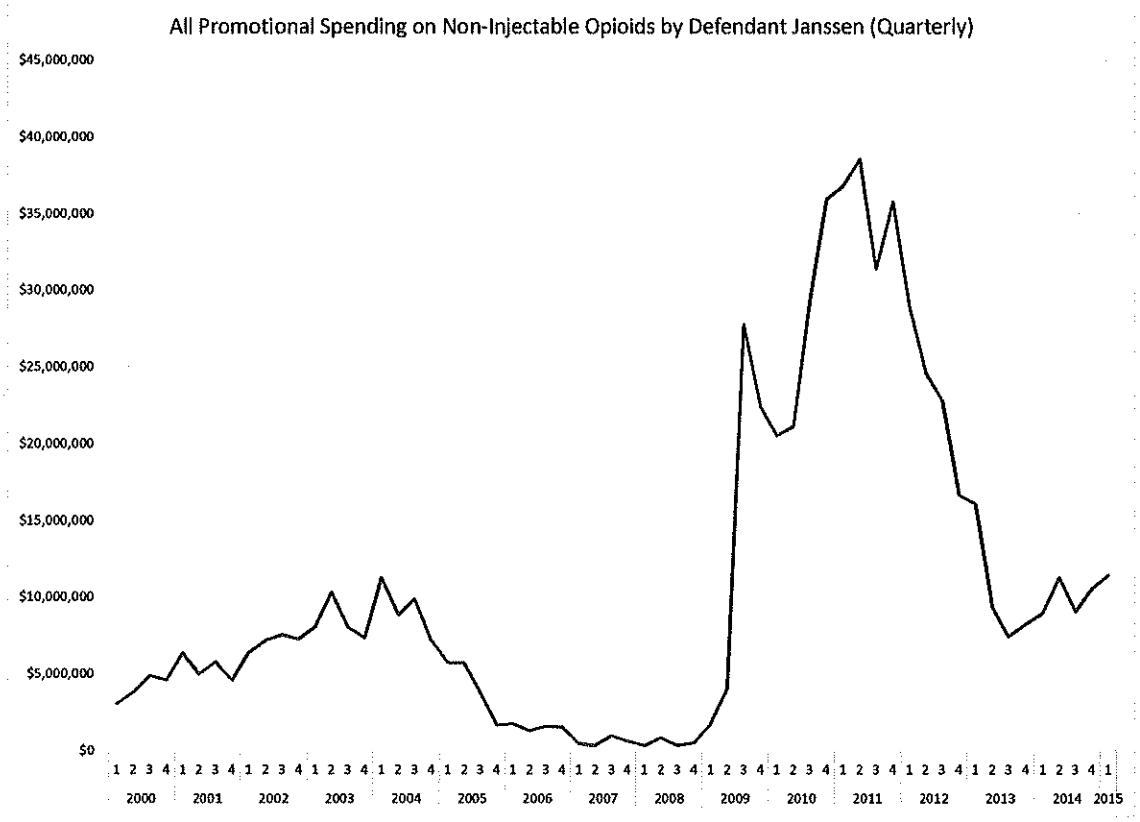
266. Cephalon's quarterly spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of nearly $9 million for one quarter of 2007 (and more than $27 million for the year), as shown below:



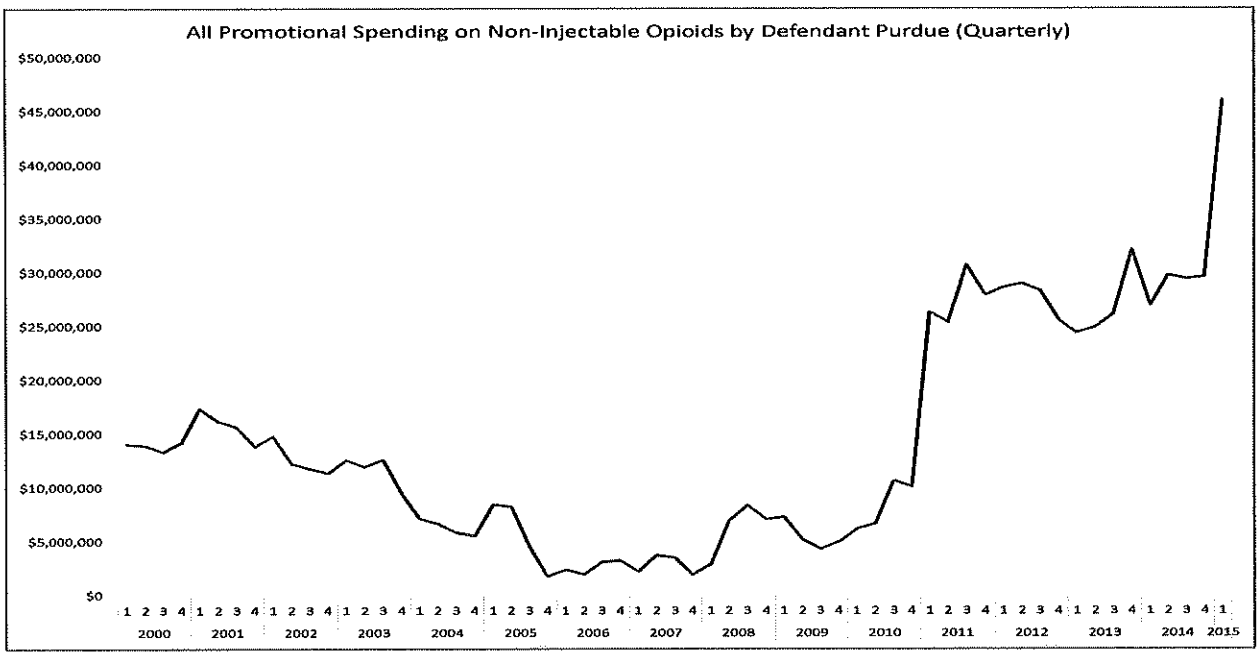
267. Endo's quarterly spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year):



268. Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011), as shown below:



269. Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above $25 million in 2011 (for a total of $110 million that year), and continues to rise, as shown below:



270. Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence.

271. In particular, the effects of sales calls on prescribers' behavior is well-documented in the literature, including a 2009 study correlating the nearly ten-fold increase in OxyContin prescriptions between 1997 and 2002 to Purdue's doubling of its sales force and trebling its sales calls.[97] A 2017 study found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers.[98] The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study involved the research of four

[97] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy,* 99 Am. J. Pub. Health 221–227 (2009).

[98] Ian Larkin et al., *Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317 J. Am. Med. Ass'n 1785 (2017).

different practices which included visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on driving drug utilization.[99] An additional study found that doctor meetings with sales representatives are related to changes in doctor prescribing practices and requests by physicians to add the drugs to hospitals' formularies.[100]

272. The U.S. Senate Homeland Security & Governmental Affairs Committee recently issued a Staff Report which noted the link between drug maker payments to prescribers and physician prescribing practices. It found that "a clear link exists between even minimal manufacturer payments and physician prescribing practices."[101] The Report quotes ProPublica findings that "doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty."

273. The sharp increase in opioid use resulting from Defendants' conduct has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including in Stark County. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[102]

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[99] Kesselheim Declaration citing Berdent ER, et al. *Information, marketing and pricing in the US antiulcer drug market.* Amer Econ Rev 1995, 85:101-105.

[100] *Id.* citing Wazana A. *Physicians and the pharmaceutical industry: is a gift ever just a gift? JAMA* 2000,283:373-80.

[101] Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization* at 7.

[102] "America's Addiction to Opioids: Heroin and Prescription Drug Abuse," *Senate Caucus on Int'l Narcotics Control*, hr'g, Testimony of Dr. Nora Volkow (May 14, 2014) available at http://www.drugcaucus.senate.gov/sites/default/files/Volkow%20Testimony.pdf.

274. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[103]

275. Scientific evidence demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[104]

276. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[105] The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[106]

277. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the

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[103] *See* n.2, *supra*.

[104] Theodore J Cicero *et al.*, *Relationship Between Therapeutic Use and Abuse* of *Opioid Analgesics in Rural, Suburban, and Urban* Locations in the United States, 16.8 Pharmacoepidemiology and Drug Safety, 827-40 (2007).

[105] Dart, MD, *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, New Engl. J. Med., 372:241-248 (Jan. 15, 2015).

[106] Califf, MD, *et al.*, *A Proactive Response to Prescription Opioid Abuse,* New Engl. J. Med. (Apr. 14, 2016).

CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[107]

278. Contrary to Defendants' misrepresentations, most of the illicit use originates from *prescribed* opioids. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet.

279. Further, people who are addicted to prescription opioid painkillers are 40 times more likely to be addicted to heroin. The CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. Roughly 80% of heroin users previously used prescription opioids. Recently, 3 people died from apparent heroin overdoses in less than a 24 hours in Stark County.

280. Ohio's Prescription Drug Abuse Task Force has found that individuals addicted to prescription opioids often transition to heroin due to its lower cost, ready availability, and similar high. Likewise, a study by the Ohio Substance Abuse Monitoring Network reported on the connection between oxycodone use and heroin addiction, finding that "[y]oung new heroin abusers seeking treatment reported OxyContin abuse prior to becoming addicted to heroin," that several reported resorting to heroin after OxyContin became too expensive or difficult to obtain, and that "[a]buse of OxyContin prior to the abuse of heroin appears to be a common pattern."[108]

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[107] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., *et al.* "Increases in drug and opioid overdose deaths—United States, 2000–2014." American Journal of Transplantation 16.4 (2016): 1323-1327.

[108] Ohio Substance Abuse Monitoring Network, OSAM Rapid Response Investigation Reveals Connection Between OxyContin Abuse and Heroin Addiction in Some Individuals, *available* at http://mha.ohio.gov/Portals/Wassets/Learning/OSAMaan02ConnxtsOxy.pdf

or

281. A relatively recent, even more deadly problem stemming from the prescription opioid epidemic involves fentanyl—a powerful opioid prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into Ohio communities, including Stark County.

282. Carfentanil, a powerful derivative of fentanyl, has increasingly been found in heroin and fentanyl sold illicitly. Carfentanil is so strong that it is typically used in veterinary medicine to sedate large wild animals such as elephants, and has been researched as a chemical weapon. A dose the size of a grain of salt can rapidly lead to deadly overdose in humans. Because of its potency, the Ohio Attorney General's website recommends that chemists and lab technicians who test for carfentanil use protective gear. As recently as January 2018, $100,000 worth of carfentanil was seized from a Stark County home. Additionally, in March of 2018, a North Canton-area resident was indicted in federal court on allegations tied to bringing them in large amounts of fentanyl and carfentanil, and selling them in Ohio communities.

283. Ohio now "leads the country in drug overdose deaths per capita, a rate that continues to rise, overwhelming families, communities, and local governments across the state."[109] In Ohio, an average of 14 people now die, per day, from fatal drug overdoses. Provisional data from the CDC showed the crisis continuing to explode during the first half of last year, with 5,232 Ohio overdose deaths recorded in the 12 months ending June 31, 2017. Further, even these grim numbers likely understate the number of lives lost due to incomplete reporting.

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http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwjIl6nDjZLaAhWSu1MKHXwmCMMQFggnMAA&url=http%3A%2F%2Fmha.ohio.gov%2FPortals%2F0%2Fassets%2FLearning%2FOSAM%2FJan02ConnxtsOxy.pdf&usg=AOvVaw0YQ8A4YVKePz9xajswyHMJ

[109] C. William Swank Program in Rural-Urban Policy, Taking Measure of Ohio's Opioid Crisis, The Ohio State University (Oct. 2017) at 1.

284. In Stark County, the number of drug-related deaths more than doubled in recent years. In 2012, 42 deaths were attributed to opioids, and another 19 people lost their lives to heroin or fentanyl overdoses. In 2016, the County saw more than a hundred people die of opioid overdoses and 83 people died heroin or fentanyl overdoses. In 2017, 144 people died of opiate-related overdoses.

285. As the crisis unfolds, tragically, more people lost their lives in the County than the morgue had room to hold. In March of 2017, the County coroner's office requested a cold-storage trailer from the Ohio Emergency Management Agency to properly house the bodies. According to an investigator for the County's coroner's office and 40 year veteran of public safety, the opioid and heroin crisis is responsible for the increase in deaths.

286. Overdose deaths are only one consequence. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of Narcan or naloxone—the antidote to opioid overdose. In 2017, County emergency room reported treating 855 drug overdoses. Further, from January to mid-July of 2018 alone, EMS providers in the County reported administering Narcan 213 times.

287. Opioid addiction is now the primary reason that Ohioans seek substance abuse treatment. In 2014, 37% of admissions for drug abuse were associated with a primary diagnosis of opioid abuse or dependence. According to a 2015 poll, 3 in 10 Ohio adults have family members or friends who have experienced problems as a result of abusing prescription pain relievers, a steep rise from only a year earlier, and 2 in 10 Ohio adults had family or friends whom they described as experiencing problems from using heroin. Of these Ohioans, 4 in 10 knew someone who had overdosed due to a pain drug, and 6 in 10 knew someone who had overdosed on heroin.

288. The County has seen a dramatic increase in the number of people seeking addiction treatment due to opioid use. According to Stark County Mental Health and Addiction Recovery, there has been a vast increase in clients treated for opioid use disorder over a ten year time span. In 2006, the number of clients who received addiction treatment for opioids was 255. In 2016, this number increased to 1,444 clients—a 505% increase.

289. Defendants' conduct has significantly harmed veterans. Sixty percent (60%) of veterans returning from deployment suffer from chronic pain, double the national average of thirty percent (30%) of U.S. citizens. Veterans are twice as likely to suffer addiction and to die from opioid abuse than non-veterans according to a 2011 Veterans Administration study. More than 28,000 veterans live in Stark County, which is home to more veterans than any other County in the State.

290. Opioids have caused injury and illness in Stark County in other respects as well. An increase in Hepatitis C, according to the CDC, is directly tied to intravenous injection of opioids. The number of cases of chronic Hepatitis C in Ohio nearly tripled from 2011-2015, an increase that resulted largely from intravenous use of drugs, including OxyContin and other prescription painkillers, stemming from the opioid epidemic. The co-morbidity is sufficiently high that the Ohio Department of Health recommends that women of childbearing age who have tested positive for drug and dependence also receive screening for Hepatitis C and HIV.

291. The deceptive marketing, overprescribing, and oversupply of opioids also had a significant detrimental impact on children in Stark County. Young children have access to opioids, nearly all of which were prescribed or supplied to adults in their household. If parents become addicted and turn to illicit opiates, children risk overdose from these drugs as well.

292. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour.

293. In Ohio, the number of infants born with NAS increased six-fold in from 2004 to 2011. From 2009 to 2014, data from seven regional hospitals showed a greater-than six-fold increased in drug-exposed infants. As a whole, the State has seen an 816% increase in the number of infants born with NAS from 2006 to 2015, with opioids and other illegal narcotics being the most commonly implicated drugs since 2009 In 2015 alone, 2,174 infants were admitted to inpatient settings for this painful condition, an average of six per day. NAS has become so prevalent in Ohio Communities that the state's Department of Health now recommends screening all newborns for this condition.

294. This dramatic rise in NAS may be described as an epidemic within an epidemic. According to the Ohio Perinatal Quality Collaborative, the "NAS epidemic is steadily increasing,

overwhelming social service systems and public payers."[110] In 2013, the average inpatient stay and bill for babies suffering from NAS was four times longer and four times higher than for other infants in Ohio. Newborns with NAS spent approximately 26,000 days in Ohio hospitals in 2014, with health care costs totaling $105 million. Ohio's healthcare system alone has contributed more than $133 million to NAS-related hospital charges in 2015. From 2011 to 2015, 97 babies were hospitalized for NAS in Stark County.

295. Further, "[c]hildren of parents addicted to opiates," have been described as the "invisible victims of the epidemic," are "flooding into the state's child protection system."[111] Statewide, the opioid epidemic is largely responsible for the 9% increase in the numbers of children - nearly 1,100 – placed in the care of Ohio child protection agencies between 2011 and 2015. Seventy percent of infants placed in Ohio's foster care system are children of parents with opioid addictions. Further, these figures do not account for children who are placed in kinship care or who receive public services without being displaced from their homes.

296. In Stark County, the number of children in foster has increased. In December 2016, the number of children in the custody of the Department of Job and Family services was approximately 360. In December 2017, the number of children in custody increased to 383. Additionally, the Department has experienced an increase in calls alleging abuse or neglect. In 2017, the Department averaged 628 calls per month, which was 60 calls higher per month than 2016. Approximately one-third of these calls involve allegations of parental drug abuse, however, this number is likely under-reported. The County is in need of additional foster homes, and Stark County

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[110] Neonatal Abstinence Syndrome Project, OPQC, Ohio Perinatal Quality Collaborative, *available at* https://opqc.net/projects/NAS.

[111] Public Children Services Association of Ohio (PCSAO), http://www.pcsao.org/programs/opiate-epidemic

Children Services describes opioids as a huge problem and one that prevents children from remaining in the home.

297. Children removed from homes with drug abuse tend to stay in foster care longer and to enter foster care having experienced more significant trauma, which makes their care more expensive. Many of these kids watched their parents overdose or die," according to the executive director of the Public Children Services Association of Ohio ("PCSAO"), a statewide membership organization for county children services agencies.[112] Children may have gone days without food or supervision, and older children may have functioned as surrogate parents to their younger siblings, reported Ohio's Attorney General.[113] A statewide report found that increasingly, children entering the foster care system from homes with drug abuse are dealing with significant mental health issues, requiring intensive treatment that may cost as much as $200 to $400 a day, because of what they have seen or experienced. Ohio has the heaviest reliance on local dollars for child protection services of any state in the nation, with counties shouldering more than half of the costs through local government funds and dedicated levies.

298. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses in other respects as well. According to a recent analysis by a Princeton University economist, approximately one out of every three working age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014-16, and 25% of the decline in labor force participation among women. Many of

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[112] Chris Stewart, *Foster Care Report: 'Many of these kids watched their parents overdose or die,'* Dayton Daily News, available at https://www.mydaytondailynews.com/news/foster-care-report-many-these-kids-watched-their-parents-overdose-die/X4ytHHs6IlO5D8GseUQclK/; http://www.pcsao.org/programs/opiate-epidemic

[113] *Id.*

those taking painkillers still said they experienced pain daily. A recent report by The Ohio State University estimated that in Ohio, in 2015 alone, "opioid overdoses resulted in $3.8 billion in lost lifetime productivity" and "[i]n total, the cost of opioid abuse and dependency ranged from $6.6 billion to $8.8 billion."[114] Locally, the president and chief executive of the Canton Regional Chamber of Commerce has described many area businesses as struggling to find candidates who can pass drug tests.

299. The County has also faced increased costs associated with the opioid crisis. According to a study released by Ohio State University, the opioid crisis costs the County up to $499 per resident, regardless of whether they used drugs or not. The study focused on costs associated with health care and treatment, criminal justice, lost productivity among opioid users, and lost productivity after a fatal overdose.

300. In 2011, the County created the Opioid Task Force to address the opioid crisis. Members of the task force include law enforcement, medical professionals, treatment providers, community leaders, and parents. The task force aims to provide resources in the community and help educate on opioid prevention and safe prescribing practices. The task force also created a fatal overdose review committee, and established a support group for individuals and family members who have been impacted by opioid addiction.

301. Beginning in 2012, the County also held an Opiate Symposium-Seminar for the State of Ohio to provide education and information on trends in the epidemic.

302. The County also seeks to reach people in need of help through a new program called Project DAWN (Deaths Avoided with Naloxone). Project Dawn is an overdose education and

[114] C. William Swank Program in Rural-Urban Policy, Taking Measure of Ohio's Opioid Crisis, The Ohio State University (Oct. 2017) at 8.

naloxone distribution program. In the program, participants learn how to recognize the symptoms and signs of an opioid overdose, make an emergency 911 call, perform rescue breathing, and administer Narcan. The program is of no cost and is available to all County residents who are 18 –years-old and over. In August 2017, DAWN was awarded $1 million by the Ohio Department of Health to expand the availability of Narcan.

303. In October of 2017, a new 16-bed detox and recovery unit at the Alliance Community Hospital more than doubled the number of publically funded in-patient detox beds in the County. The Stark Mental Health and Addiction Recovery (Stark MHAR) supplied $200,000 in start-up costs, and the County also provides subsidies covering a number of patients using the detox center. In the spring of 2018, the Deliverance House II, a 17-bed facility for women undergoing detox and recovery, opened in the County. The County supported its services through $181,000 in start-up costs, with an additional $200,000 to provide operating expenses for the first year.

304. Stark MHAR has also been a hub for resources and treatment in the County. The agency funds inpatient and outpatient treatment centers, prevention materials, community information festivals, pamphlets, billboards, and training. Funding this work has cost over $4.46 million since 2015.

305. Drug take back boxes are now available at 18 locations throughout the County. From 2013 to 2017, the County has collected more than 24,280 pounds of pills. The boxes fill, and a local steel mill conducts a pill burn, approximately once a month. The County also conducts a drug take bac-day once a year. Since 2010, it has collected 28,494 pounds of pills and syringes during dedicated Stark County Drug Take Back Days and an additional 18,061 pounds between May 2013 and December 31, 2016 in collection boxes.

306. The County established a new agency, the Treatment Accountability for Safer Communities Agency ("TASC"), which provides peer support to people working to overcome addiction. The agency offers various services to community members, including transportation for meetings and appointments, sponsorship through sobriety, and assessments for drug abuse. Most recently, it placed peers in emergency rooms to be prepared to help when an overdose call comes in. This new program cost more than $399,000 from April 2017 to May 2018 and has increased the number of people getting into treatment and connected to additional treatment.

307. The County operates an Opiate Hotline, designed for those in crisis and in need of assistance to recover from addiction. A pilot program in the jail trains individuals to use Narcan kits and provides kits to people considered at risk of overdose following release. Another pilot program connected to the jail provides Vivitrol as a way of helping with withdrawal from opiates and aiding in recovery from addiction.

308. In addition to its own efforts, the County funds the Stark Wide Approach to Prevention ("SWAP"), a needle exchange program used for the prevention of disease and harm reduction, and administered through the Canton City Health Department. The program has served more than 190 people, and made 35 substance use referrals. The County also supports a program helping families combat heroin addiction and abuse, which uses an annual event to fund day camps throughout the summer.

309. The County has expended substantial resources combatting the opioid epidemic, which has placed significant burdens on its social, criminal justice, and emergency response services. Since, 2015, it has spent more than $73,000 on Narcan alone. Further, from January 1, 2011 until January 1, 2018, the County health plan spent $235,441.53 on opioid medications. The County has had to pay for opioid prescriptions, related doctor visits, and opioid addiction treatment

services through its self-funded health care and workers compensation programs. Even the County library has been impacted. In response to needles found laying about, the Stark County District Library installed containers for safe disposal.

K. STATUTES OF LIMITATIONS ARE TOLLED AND DEFENDANTS ARE ESTOPPED FROM ASSERTING STATUTES OF LIMITATIONS AS DEFENSES.

1. Continuing Conduct

310. Plaintiffs continue to suffer harm from Defendants' unlawful actions.

311. The continued tortious and unlawful conduct by Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. Defendants' wrongdoing and unlawful activity has not ceased. The public nuisance remains unabated, as does the conduct causing the nuisance.

2. Equitable Estoppel and Fraudulent Concealment

312. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive Plaintiffs and to purposefully conceal their unlawful conduct and fraudulently assure the public, including state and local governments, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered distributor status in Ohio and continuing to generate profits. Notwithstanding the allegations set forth above, Defendants affirmatively assured the public, and state and local governments, that they are working to curb the opioid epidemic.

313. Defendants were deliberate in taking steps to conceal their conspiratorial behavior and active role in the oversupply of opioids, which fueled the opioid epidemic.

314. As set forth herein, Defendants concealed from Plaintiffs the existence of the Plaintiffs' claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the public that their legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers and the public, including Plaintiffs, and deprived Plaintiffs of actual or implied knowledge of facts sufficient to put the Plaintiffs on notice of potential claims.

315. Plaintiffs did not discover the nature, scope, and magnitude of Defendants' misconduct, and its full impact on Plaintiffs, and Plaintiffs could not have acquired such knowledge earlier through the exercise of reasonable diligence.

316. Further, Defendants have also concealed and prevented discovery of information that will confirm their identities and the extent of their wrongful and illegal activities.

317. Defendants made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing, including marketing by third parties they sponsored, was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Defendants of this, and likewise, Purdue and Teva paid hundreds of millions of dollars to address similar misconduct that occurred before 2008. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of

addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on existing medical evidence that conclusively exposes the known falsity of Defendants' misrepresentations.

318. Notwithstanding this knowledge, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful and fraudulent conduct. Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third party advocates, and professional associations. Defendants purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of their false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue, Endo, Teva, and Janssen, masked or never disclosed their role in shaping, editing, and approving the content of this information.

319. Defendants thus successfully concealed from the medical community, patients, and Plaintiffs facts sufficient to arouse suspicion of the claims that Plaintiffs now assert. Plaintiffs did not know of the existence or scope of Defendants' fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

CAUSES OF ACTION

COUNT I
Statutory Public Nuisance
(Against All Defendants)
(Brought by the County of Stark, the City of Canton, and The State of Ohio ex rel. John D. Ferrero, the County Prosecutor of Stark County, Kristen Bates Aylward, the Director of Law for the City of Canton, Director of Law for the City of Canton, Andrea Scassa, Director of Law for the City of Massillon, and Jennifer L. Arnold, Director of Law for the City of Alliance, each as the Plaintiff in this Count)

320. Plaintiffs incorporate the allegations within all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

321. The Prosecuting Attorney for Stark County, John D. Ferrero, the Director of Law for the City of Canton, Kristen Bates Aylward, the Director of Law for the City of Massillon, Andrea Scassa, and the Director of Law for the City of Alliance, Jennifer L. Arnold, bring this claim in the name of the State of Ohio pursuant to the statutory authority granted under R.C. § 3767.03, to abate a public nuisance and to enjoin further maintenance of the nuisance. R.C. § 3767.03 provides: "Whenever a nuisance exists the attorney general; the village solicitor, city director of law, or other similar chief legal officer of the municipal corporation in which the nuisance exists; the prosecuting attorney of the County in which the nuisance exists; the law director of a township that has adopted a limited home rule government under Chapter 504. of the Revised Code; or any person who is a citizen of the County in which the nuisance exists may bring an action in equity in the name of the state, upon the relation of the attorney general; the village solicitor, city director of law, or other similar chief legal officer of the municipal corporation; the prosecuting attorney; the township law director; or the person, to abate the nuisance and to perpetually enjoin the person maintaining the nuisance from further maintaining it."

322. The Prosecuting Attorney for Stark County also brings this claim in the name of the State of Ohio pursuant to the statutory authority granted under R.C. § 4729.35 to enjoin a violation of that statute.

323. The Cities of Canton, Massillon, and Alliance, by and through their respective Directors of Law, Kristen Bates Aylward, Andrea Scassa, and Jennifer L. Arnold, in the name of the State of Ohio and/or on behalf of the municipal corporations and their residents, also bring this claim pursuant to its statutory authority under R.C. § 715.44 to: (A) [a]bate any nuisance and

prosecute in any court of competent jurisdiction, any person who creates, continues, contributes to, or suffers such nuisance to exist; [and] (C) [p]revent injury and annoyance from any nuisance . . . ."

324. Ohio statutory law provides that "[a]s used in all sections of the Revised Code relating to nuisances . . . (C) "Nuisance" means any of the following: . . . (1) [t]hat which is defined and declared by statutes to be a nuisance . . . ." R.C. § 3767.01

325. Ohio statutory law "declare[s] to be inimical, harmful, and adverse to the public welfare of the citizens of Ohio and to constitute a public nuisance" "[t]he violation by a pharmacist or other person of any laws of Ohio or of the United States of America or of any rule of the board of pharmacy controlling the distribution of a drug of abuse as defined in section 3719.011 of the Revised Code . . . ." R.C. § 4729.35.

326. Opioids are "a drug of abuse" as defined in R.C. § 3719.011.

327. Under R.C. § 3767.02, "Any person, who uses, occupies, establishes, or conducts a nuisance, or aids or abets in the use, occupancy, establishment, or conduct of a nuisance; the owner, agent, or lessee of an interest in any such nuisance; any person who is employed in that nuisance by that owner, agent, or lessee; and any person who is in control of that nuisance is guilty of maintaining a nuisance and shall be enjoined as provided in sections 3767.03 to 3767.11 of the Revised Code."

328. Defendants are persons who have established or conducted a nuisance, who have aided or abetted in the establishment or conduct of a nuisance, and/or who are in control of a nuisance and guilty of maintaining a nuisance; as defined in R.C. § 3767.02.

329. Defendants are persons who have violated, and/or who have aided and abetted the violation of the laws of Ohio or of the United States of America or of any rule of the board of pharmacy controlling the distribution of a drug of abuse as defined in R.C. § 3719.011.

330. In the distribution and sale of opioids in Stark County, Defendants violated and/or aided and abetted the violation of Ohio law, including, but not limited to, R.C. § 4729.01(F), R.C. §§ 4729.51-4729.53, and "O.A.C. §§ 4729-9-12, 4729-9-16, 4729-9-28, and federal law, including, but not limited to, 21 U.S.C.A. § 823 and 21 C.F.R. § 1301.74.

331. Defendants' unlawful conduct includes violating and/or aiding and abetting the violation of federal and Ohio statutes and regulations, including the controlled substances laws, by, *inter alia*:

a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to stop or suspend shipments of suspicious orders; and

d. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

332. In the distribution and sale of opioids in Ohio and Stark County, Defendants violated and/or aided and abetted violations of R.C. § 2925.02(A), which states: "No person shall knowingly do any of the following:

(1) By force, threat, or deception, administer to another or induce or cause another to use a controlled substance; . . . or

(3) By any means, administer or furnish to another or induce or cause another to use a controlled substance, and thereby cause serious physical harm to the other person, or cause the other person to become drug dependent."

333. The exemption in R.C. § 2925.02 only applies to drug wholesalers and distributors when their "conduct is in accordance with Chapters R.C. 3719., 4715., 4723., 4729., 4730., 4731., and 4741." R.C. § 2925.02(B). Defendants are not in compliance with said Chapters and have thereby forfeited the protection provided by the exception.

334. Defendants' conduct entails a pervasive pattern and practice of violating the statutes and regulations set forth above. Defendants' systemic failure to adhere to Ohio and federal controlled substances statutes and regulations has created an ongoing, significant, unlawful, and unreasonable interference with the public health, welfare, safety, peace, comfort, and convenience in Plaintiffs' communities.

335. Defendants had control over their conduct in Stark County and that conduct has had an adverse effect on the public right. Defendants controlled their deceptive advertising and efforts to mislead the public, including their acts and omissions in detailing by their sales representatives, online communications, publications, Continuing Medical Education programs and other speaking events, and other means described in this Complaint. Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Each of the Defendants controlled the systems they developed to prevent diversion, and whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

336. The nuisance created by Defendants' conduct is abatable.

337. Defendants' misconduct alleged in this case is ongoing and persistent.

338. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not

part of the normal and expected costs of a local government's existence. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

339. Plaintiffs have incurred expenditures for special programs over and above its ordinary public services.

340. The unlawful conduct of each Defendant was a substantial factor in producing harm to the Plaintiffs.

341. Plaintiffs seeks abatement, recovery of abatement costs, injunctive relief, and to prevent injury and annoyance from any nuisance.

342. Plaintiffs seek all other legal and equitable relief as allowed by law.

COUNT II
Common Law Absolute Public Nuisance
(Against All Defendants)
(Brought by the County of Stark Board of Commissioners and the Cities of Canton, Massillon, and Alliance, the Plaintiffs in this Count)

343. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein unless inconsistent with the allegations in this Count, and further alleges:

344. Defendants created and maintained a public nuisance which proximately caused injury to Plaintiffs.

345. A public nuisance is an unreasonable interference with a right common to the general public.

346. Defendants have created and maintained a public nuisance by marketing, distributing, and selling opioids in ways that unreasonably interfere with the public health, welfare, and safety in Plaintiffs' communities, and Plaintiffs and their residents have a common right to be

free from such conduct and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

347. The public nuisance is an *absolute* public nuisance because Defendants' nuisance-creating conduct was intentional and unreasonable and/or violated statutes which established specific legal requirements for the protection of others.

348. Defendants have created and maintained an absolute public nuisance through their ongoing conduct of marketing, distributing, and selling opioids, which are dangerously addictive drugs, in a manner which upon information and belief, caused prescriptions and sales of opioids to skyrocket in Stark County, flooded Plaintiffs' communities with opioids, and facilitated and encouraged the flow and diversion of opioids into an illegal, secondary market, resulting in devastating consequences to Plaintiffs and their residents.

349. Defendants know, and have known, that their intentional, unreasonable, and unlawful conduct will cause, and has caused, opioids to be used and possessed illegally and that their conduct has produced an ongoing nuisance that has had, and will continue to have, a detrimental effect upon the public health, welfare, safety, peace, comfort, and convenience of Plaintiffs and their residents.

350. Defendants' conduct has created an ongoing, significant, unlawful, and unreasonable interference with rights common to the general public, including the public health, welfare, safety, peace, comfort, and convenience of Plaintiffs and their residents. *See* Restatement (Second) of Torts § 821B.

351. The interference is unreasonable because Defendants' nuisance-creating conduct:

a. Involves a significant interference with the public health, the public safety, the public peace, the public comfort, and/or the public convenience;

b. At all relevant times was and is proscribed by state and federal laws and regulations; and/or

c. Is of a continuing nature and, as Defendants know, has had and is continuing to have a significant effect upon rights common to the general public, including the public health, the public safety, the public peace, the public comfort, and/or the public convenience.

352. The significant interference with rights common to the general public is described in detail throughout this Complaint and includes:

a. The creation and fostering of an illegal, secondary market for prescription opioids;

b. Easy access to prescription opioids by children and teenagers;

c. A staggering increase in opioid abuse, addiction, overdose, injuries, and deaths;

d. Infants being born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;

e. Employers have lost the value of productive and healthy employees; and

f. Increased costs and expenses for Plaintiffs relating to healthcare services, law enforcement, the criminal justice system, social services, and education systems.

353. Defendants intentionally and unreasonably and/or unlawfully marketed and pushed as many opioids onto the market as possible, fueling addiction to and diversion of these powerful narcotics, resulting in increased addiction and abuse, an elevated level of crime, death and injuries to the residents of Plaintiffs' communities, a higher level of fear, discomfort and inconvenience to the residents of Plaintiffs' communities, and direct costs to Plaintiffs.

354. Each Defendant is liable for creating the public nuisance because the intentional and unreasonable and/or unlawful conduct of each Defendant was a substantial factor in producing the public nuisance and harm to Plaintiffs.

355. A violation of any rule or law controlling the sale and/or distribution of a drug of abuse in Plaintiffs' communities constitutes an absolute public nuisance. *See e.g.* R.C. § 4729.35 ("The violation by a . . . person of any laws of Ohio or of the United States of America or of any rule of the board of pharmacy controlling the distribution of a drug of abuse . . . constitute[s] a public nuisance[.]").

356. In the sale and distribution of opioids in Ohio and Plaintiffs' communities, Defendants violated federal law, including, but not limited to, 21 U.S.C.A. § 823 and 21 C.F.R. § 1301.74, and Ohio law, including, but not limited to, R.C. § 4729.01(F), R.C. §§ 4729.51-4729.53, and O.A.C. §§ 4729-912, 4729-9-16, and 4729-9-28.

357. Defendants' unlawful nuisance-creating conduct includes violating federal and Ohio statutes and regulations, including the controlled substances laws, by:

a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders; and

g. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

358. Defendants' intentional and unreasonable nuisance-creating conduct, for which the gravity of the harm outweighs the utility of the conduct, includes:

a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders; and

g. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

359. Defendants intentionally and unreasonably distributed and sold opioids that Defendants knew would be diverted into the illegal, secondary market and would be obtained by persons with criminal purposes.

360. As evidence of addiction and abuse of opioids widened, Defendants were obligated to rein in their supply, prevent diversion, and mitigate the harms from opioid overuse and abuse, but intentionally and unreasonably failed to do so.

361. Defendants intentionally and unreasonably engaged in a deceptive marketing scheme that was designed to, and successfully did, change the perception of opioids and upon information and belief, cause their prescribing and sales to skyrocket in Plaintiffs' communities.

362. Defendants intentionally and unreasonably misled Plaintiffs, healthcare providers, and the public about the risks and benefits of opioids, including minimizing the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain.

363. Defendants violated Ohio and federal statutes and regulations, including the controlled substances laws, by engaging in the deceptive marketing of opioids, as described in this Complaint.

364. In the distribution and sale of opioids in Ohio and Plaintiffs' communities, Defendants violated and/or aided and abetted violations of R.C. § 2925.02(A), which states: "No person shall knowingly do any of the following:

> (1) By force, threat, or deception, administer to another or induce or cause another to use a controlled substance; . . . or
>
> (3) By any means, administer or furnish to another or induce or cause another to use a controlled substance, and thereby cause serious physical harm to the other person, or cause the other person to become drug dependent."

365. Defendants are in the business of manufacturing, marketing, selling and/or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.

366. Indeed, opioids are akin to medical grade heroin. Defendants' wrongful conduct of deceptively marketing and pushing as many opioids onto the market as possible led directly to the public nuisance and harm to the Plaintiffs—exactly as would be expected when medical-grade heroin in the form of prescription opioids are deceptively marketed, flood the community, and are diverted into an illegal, secondary market.

367. Defendants had control over their conduct in Plaintiffs' communities that conduct has had an adverse effect on rights common to the general public. Defendants controlled their deceptive advertising and efforts to mislead the public, including their acts and omissions in detailing by their sales representatives, online communications, publications, Continuing Medical Education programs and other speaking events, and other means described in this Complaint. Each of the Defendants controlled the systems they developed to prevent diversion, including whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

368. It was reasonably foreseeable that Defendants' actions and omissions would result in the public nuisance and harm to the Plaintiffs described herein.

369. Because of Defendants' deceptive marketing of opioids and because of Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

370. The public nuisance created by Defendants' actions is substantial and unreasonable. It has caused and continues to cause significant harm to Plaintiffs and the harm inflicted outweighs any offsetting benefit.

371. The externalized risks associated with Defendants' nuisance-creating conduct as described herein greatly exceed the internalized benefits.

372. As a direct and proximate result of Defendants' tortious conduct and the public nuisance created by Defendants, Plaintiffs have taken proactive measures to abate the public nuisance, and Plaintiffs seek to expand these efforts.

373. The nuisance created by Defendants' conduct is abatable.

374. Defendants' misconduct alleged in this case is ongoing and persistent.

375. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

376. Plaintiffs have incurred expenditures for special programs over and above its ordinary public services.

377. Plaintiffs seek to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and unreasonable interference with rights common to the general public.

378. Plaintiffs are asserting their own rights and interests and its claims are not based upon or derivative of the rights of others.

379. The tortious conduct of each Defendant was a substantial factor in creating the absolute public nuisance.

380. The tortious conduct of each Defendant was a substantial factor in producing harm to Plaintiffs.

381. Plaintiffs have suffered an indivisible injury as a result of the tortious conduct of Defendants.

382. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

383. Plaintiffs assert this Cause of Action as a common law tort claim for absolute public nuisance and not as a "product liability claim" as defined in R.C. § 2307.71. In this Count, Plaintiffs do not seek damages for death, physical injury to person, emotional distress, or physical damage to property, as defined under the Ohio Product Liability Act.

384. Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, , attorney fees and costs, and pre- and post-judgment interest.

COUNT III
Common Law Qualified Public Nuisance
(Against All Defendants)

(Brought by the County of Stark Board of Commissioners and the Cities of Canton, Massillon, and Alliance, the Plaintiffs in this Count)

385. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein unless inconsistent with the allegations in this Count, and further alleges:

386. The excessive and unreasonable oversupply of opioids in Plaintiffs' communities constitutes a public nuisance in that it unreasonably interfered with rights common to the general public, including the public health, welfare, safety, peace, comfort, and convenience of Plaintiffs and their residents. *See* Restatement (Second) of Torts § 821B.

387. The significant interference with rights common to the general public is described in detail throughout this Complaint and includes:

a. A staggering increase in opioid abuse, addiction, overdose, injuries, and deaths throughout Plaintiffs' communities, including infants who are born addicted to opioids due to prenatal exposure;

b. A corresponding increase in abuse, addiction, overdose, injuries and deaths related to the transition from opioid pills to heroin, fentanyl, and carfentanyl;

c. The necessity for governmental intervention from Federal, State and Local governments to provide services for, among other things, healthcare, law enforcement, criminal justice, social services, and education related to the Opioid epidemic;

388. Defendants' conduct in marketing and selling opioids created or contributed to the creation or maintenance of this public nuisance. Defendants' conduct caused prescriptions and sales of opioids to skyrocket in Stark County and flooded Plaintiffs' communities with opioids, and facilitated and encouraged the flow and diversion of opioids into an illegal, secondary market, resulting in devastating consequences to Plaintiffs and their residents.

389. Defendants created or contributed to the creation and/or maintenance of the public nuisance by:

a. negligently, unreasonably and/or unlawfully engaging in a deceptive marketing scheme that was designed to, and successfully did, change the perception of opioids and upon information and belief, cause their prescribing and sales to skyrocket in Plaintiffs' communities;

b. negligently, unreasonably and/or unlawfully misleading Plaintiffs, healthcare providers, and the public about the risks and benefits of opioids, including minimizing the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain;

c. violating Ohio and federal statutes and regulations, including the controlled substances laws, by engaging in the deceptive marketing of opioids and/or failing to maintain effective controls against diversion, as described in this Complaint;

d. negligently, unreasonably and/or unlawfully deceptively marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain;

e. negligently, unreasonably and/or unlawfully marketing or selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

f. negligently, unreasonably and/or unlawfully marketing or selling opioids without maintaining effective controls against the diversion of opioids;

g. negligently, unreasonably and/or unlawfully failing to effectively monitor for suspicious orders;

h. negligently, unreasonably and/or unlawfully failing to investigate suspicious orders;

i. negligently, unreasonably and/or unlawfully failing to report suspicious orders;

j. negligently, unreasonably and/or unlawfully failing to stop or suspend shipments of suspicious orders; and

k. negligently, unreasonably and/or unlawfully marketing or and/or selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

390. Defendants know, and should have known, that their unreasonable, and unlawful conduct does cause, has caused, and will continue to cause, excessive availability of opioids in Plaintiffs' communities and that their conduct has produced an ongoing nuisance that has had, and will continue to have, a detrimental effect upon the public health, welfare, safety, peace, comfort, and convenience of Plaintiffs and their residents.

391. Despite this knowledge, Defendants negligently, unreasonably and/or unlawfully marketed and pushed as many opioids onto the market as possible, fueling addiction to and diversion of these powerful narcotics.

392. Defendants owed Plaintiffs legal duties, including:

a. a preexisting duty, to not expose Plaintiffs and their residents to an unreasonable risk of harm. Defendants' conduct, as detailed herein, breached that duty;

b. a duty to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in manufacturing, advertising, marketing and selling opioids; and

c. a duty not to breach the standard of care established under Ohio law and the federal Controlled Substances Act ("CSA") and their respective implementing regulations to report suspicious prescribing and to maintain systems to detect and report such activity.

393. As evidence of addiction and abuse of opioids widened, Defendants were obligated to rein in their supply, prevent diversion, and mitigate the harms from opioid overuse and abuse, but intentionally or negligently and unreasonably failed to do so.

394. The degree of care the law requires is commensurate with the risk of harm the conduct creates. Defendants' conduct in marketing and selling dangerously addictive drugs requires a high degree of care and places them in a position of great trust and responsibility *vis a vis* the Plaintiffs. Their duty cannot be delegated.

395. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in selling dangerous controlled substances.

396. Plaintiffs do not only allege that Defendants were negligent only for failure to protect from harm. Defendants engaged in affirmative conduct, the foreseeable result of which was to cause harm to Plaintiffs.

397. It was reasonably foreseeable that Defendants' actions and omissions would result in the public nuisance and harm to Plaintiffs described herein. Reasonably prudent manufacturers of prescription opioids would have anticipated that the conduct alleged herein would create a public nuisance in the Plaintiffs' communities, and that the public nuisance created would unreasonably interfere with the public health, safety, comfort and convenience of Plaintiffs and their residents.

398. Defendants had control over their conduct in Plaintiffs' communities and that conduct has created a public nuisance, unreasonably interfering with rights common to the general public. Defendants controlled their deceptive advertising and efforts to mislead the public and physicians, including their acts and omissions in detailing by their sales representatives, online communications, publications, Continuing Medical Education programs and other speaking events, and other means described in this Complaint. Defendants also had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Each of the Defendants controlled the systems it developed to prevent diversion, including whether it filled orders it knew or should have known were likely to be diverted or fuel an illegal market.

399. The public nuisance created by Defendants' actions is substantial and unreasonable. It has caused and continues to cause significant harm to Plaintiffs and the harm inflicted outweighs any offsetting benefit.

400. As a direct and proximate result of Defendants' tortious conduct and the public nuisance created by Defendants, the Plaintiffs have taken proactive measures to abate the public nuisance, and the Plaintiffs seek to expand these efforts.

401. The nuisance created by Defendants' conduct is abatable.

402. Defendants' misconduct alleged in this case is ongoing and persistent.

403. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

404. The Plaintiffs have incurred expenditures for special programs over and above its ordinary public services.

405. The Plaintiffs seek to abate the nuisance created by the Defendants' unreasonable, unlawful, negligent, ongoing, continuing, and persistent actions and omissions and unreasonable interference with rights common to the general public.

406. The Plaintiffs' claims are not based upon or derivative of the rights of others.

407. The tortious conduct of each Defendant was a substantial factor in creating the qualified public nuisance.

408. The qualified public nuisance was a substantial factor in producing harm to the Plaintiffs.

409. The Plaintiffs have suffered an indivisible injury as a result of the tortious conduct of Defendants.

410. Each Defendant is joint and severally liable for creating the public nuisance.

411. The Plaintiffs assert this Cause of Action as a common law tort claim for qualified public nuisance and not as a "product liability claim" as defined in R.C. § 2307.71. In this Count, the Plaintiffs do not seek damages for death, physical injury to person, emotional distress, or physical damage to property, as defined under the Ohio Product Liability Act.

412. The Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, attorney fees and costs, and pre- and post-judgment interest.

COUNT IV
Ohio Corrupt Practices Act ("OCPA")
R.C. 2923.31 *et seq.*
(Against Purdue, Teva, Janssen, Endo, and Mallinckrodt (the "Opioid Marketing Enterprise"))
(Brought by the County of Stark Board of Commissioners and the Cities of Canton, Massillon, and Alliance, the Plaintiffs in this Count)

413. The Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

414. Defendants Purdue, Teva, Janssen, Endo, and Mallinckrodt are "persons" within the meaning of R.C. 2923.31(G) who conducted the affairs of an enterprise through a pattern of corrupt activity, hereinafter the "Opioid Marketing Enterprise," in violation of R.C. 2923.31.

415. Plaintiffs are "person[s]," as that term is defined in R.C. 2923.31, who was injured as a result of Defendants' wrongful conduct.

416. Under R.C. 2923.32:

> (A)(1) No person employed by, or associated with, any enterprise shall conduct or participate in, directly or indirectly, the affairs of the enterprise through a pattern of corrupt activity or the collection of an unlawful debt.
>
> (2) No person, through a pattern of corrupt activity or the collection of an unlawful debt, shall acquire or maintain, directly or indirectly, any interest in, or control of, any enterprise or real property.
>
> (3) No person, who knowingly has received any proceeds derived, directly or indirectly, from a pattern of corrupt activity or the collection of any unlawful debt, shall use or invest, directly or indirectly, any part of those proceeds, or any proceeds derived from the use or investment of any of those proceeds, in the acquisition of any title to, or any right, interest, or equity in, real property or in the establishment or operation of any enterprise.

A. Description of the Enterprise

417. Defendants were members of a legal entity enterprise within the meaning of R.C. 2923.31(C). Defendants formed an association-in-fact enterprise – sometimes referred to in this Complaint as the "Opioid Marketing Enterprise." The Opioid Marketing Enterprise consists of Defendants, including their employees and agents, and the front groups and KOLs described above.

418. Alternatively, each of the Defendants constitutes a single legal entity or associated-in-fact "enterprise" within the meaning of R.C. 2923.31(C), through which the members of the enterprise conducted a pattern of corrupt activity. The Opioid Marketing Enterprise is an ongoing and continuing business organization that created and maintained systematic links for a common purpose: to ensure the prescription of opioids for chronic pain.

419. Defendants formed the Opioid Marketing Enterprise for the purpose of unlawfully increasing demand for, and thus sales of and revenues and profits from prescription opioids by maintaining an oversupply of prescription opioids through illegal practices, including committing fraud and drug offenses (as laid out above and below). Defendants, through the Opioid Marketing Enterprise, concealed the true risks and dangers of opioids from the medical community and the

public, including the Plaintiffs, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each Defendant; (b) was separate and distinct from the pattern of corrupt activity in which Defendants engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the Defendants; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise, including between the Defendants and each of the Front Groups and KOLs; (e) had sufficient longevity for the enterprise to pursue its purpose and functioned as a continuing unit.

420. Upon information and belief, each of the Defendants in the Opioid Marketing Enterprise had a systematic link to each other through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by these Defendants. They coordinated for example, by funding the same front groups and unbranded publications. Their coordination can also be inferred through the consistent misrepresentations described in this Complaint. Further, the Defendants coordinated through groups such as the PCF; this coordination in lobbying is additional evidence that they engaged in other concerted efforts as well.

421. Through their personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise's common purpose.

422. Upon information and belief, Defendants exerted substantial control over the Opioid Marketing Enterprise through communications with each other, with the front groups, and with KOLs described in this Complaint.

423. There was, upon information and belief, regular communication between Defendants, Front Groups and KOLs, in which information was shared, misrepresentations are coordinated, and payments were exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the repeated and continuing use of the wires and mail in which Defendants, Front Groups, and KOLs share information regarding overcoming objections and resistance to the use of opioids for chronic pain. The Defendants, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

424. But for the Opioid Marketing Enterprise's unlawful fraud, the Front Groups would have had incentives to disclose the deceit by the Defendants and the Opioid Marketing Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

425. Taken together, the interaction and length of the relationships between and among the Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry with a common interest in preserving and expanding a broader market for opioids. Upon information and belief, the PCF is but an example of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrate that the leaders of each of the Defendants communicated and cooperated.

B. Conduct of the Enterprise

426. During the time period alleged in this Complaint, Defendants exerted control over, conducted and/or participated in the Opioid Marketing Enterprise by fraudulently marketing

opioids for the treatment of chronic pain. In devising and executing the illegal scheme, the members of the Opioid Marketing Enterprise devised and knowingly carried out a material scheme and/or artifice to defraud the Plaintiffs and the public to obtain money by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the risks, benefits, and superiority of opioids in general and their opioids in particular.

427. In addition, as part of this scheme, Purdue misled the public regarding its compliance with its obligations to maintain effective controls against diversion of their prescription opioids.

C. Pattern of Corrupt Activity

428. Defendants conducted and participated in the conduct of the affairs of the Opioid Marketing Enterprise, through a pattern of corrupt activity as defined in R.C. 2923.31(E) & (I)(2).

429. Corrupt activities as defined in R.C. 2923.31(I) include, among other things: engaging in, attempting to engage in, conspiring to engage in, or soliciting, coercing, or intimidating another person to engage in any conduct defined as racketeering activity under the Organized Crime Control Act of 1970, 84 Stat. 941, 18 U.S.C. 1961(1)(B), (1)(C), (1)(D), and (1)(E), as amended; and, any "violation of section . . 2913.05."

430. A "'pattern of corrupt activity' means two or more incidents of corrupt activity, whether or not there has been a prior conviction, that are related to the affairs of the same enterprise, are not isolated, and are not so closely related to each other and connected in time and place that they constitute a single event." R.C. 2923.31(E).

431. Incidents of corrupt activity include, but are not limited to:

Mail Fraud. The members of Opioid Marketing Enterprise violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, fraudulent materials via U.S. mail or commercial interstate carriers for the purpose of selling opioids for chronic pain.

Wire Fraud: The members of Opioid Marketing Enterprise violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, fraudulent materials by wire for the purpose of selling opioids for chronic pain.

Telecommunications Fraud: The members of Opioid Marketing Enterprise violated R.C. 2913.05 by "knowingly disseminat[ing], transmit[ing], or caus[ing] to be disseminated or transmitted by means of a wire, radio, satellite, telecommunication, telecommunications device, or telecommunications service any writing, data, sign, signal, picture, sound, or image with purpose to execute or otherwise further the scheme to defraud."

Violation of Controlled Substances Act. The members of the Opioid Marketing Enterprise violated 21 U.S.C. § 483(a)(4), which makes it unlawful "for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information form, any application, report, record or other document required to be made, kept or filed under this subchapter," and a violation of which is punishable by up to four years in jail, *see* 21 U.S.C. § 483(d)(1), making it a felony.

432. Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in furtherance of these Defendants' fraudulent scheme and common course of conduct to expand the market for their opioids and increase their profits through misleading and deceptive marketing. This conduct in furtherance of the Opioids Marketing Enterprise likely involved thousands of separate communications.

433. The multiple acts of corrupt activity which the members of the Opioid Marketing Enterprise committed, or aided or abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of corrupt activity."

434. Defendants' control and participation in the Opioid Marketing Enterprise were necessary for the successful activity in which these Defendants engaged that included, but was not limited to the acts detailed above and the following acts:

a. Defendants created a body of deceptive and unsupported medical and popular literature about opioids that: (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to be relied upon by physicians and patients;

b. Defendants selected, cultivated, promoted, and paid the KOLs based on their willingness to communicate and distribute these Defendants' messages about the use of opioids for chronic pain;

c. Defendants provided substantial opportunities for KOLs to participate in research studies on topics these Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

d. Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs supportive of the use of opioids for chronic pain;

e. Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be publications put out by independent front groups,;

f. Defendants sponsored CME programs put on by front groups that focused exclusively on the use of opioids for chronic pain; and

g. Defendants developed and disseminated pro-opioid treatment guidelines.

435. The Opioid Marketing Enterprise had a hierarchical decision-making structure that was headed by Defendants and corroborated by the KOLs and Front Groups. The Defendants controlled representations made about their opioids and their drugs, doled out funds to pharmacy benefit managers, and payments to KOLs, and ensured that representations made by KOLs, Front Groups, and Defendants' sales detailers were consistent with the Defendants' messaging throughout the United States and Ohio. The Front Groups and KOLS in the Opioid Marketing Enterprise were dependent on the Defendants for their financial structure and for career development and promotion opportunities.

436. Defendants concealed their relationship to and control of front groups and KOLs, who appeared to be independent but were not, from the Plaintiffs and the public at large; and Defendants intended that front groups and KOLs would distribute promotional and other materials that misrepresented the risks, benefits, and superiority of opioids.

437. Defendants worked together with each other through the Front Groups that they jointly funded and through which they collaborated on the joint promotional materials described above.

438. The front groups also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The front groups promised to, and did, make representations regarding Defendants' opioids, and opioids generally that were consistent with Defendants' messages;

b. The front groups distributed promotional and other materials which deceptively claimed that opioids could be safely used for chronic pain and that the benefits of using opioids for chronic pain outweighed the risks; and

c. The front groups concealed their connections to Defendants.

439. Meanwhile, these front groups, "with their large numbers and credibility with policymakers and the public—have 'extensive influence in specific disease areas.'"[115] The larger front groups "likely have a substantial effect on policies relevant to their industry sponsors."[116] "By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."[117]

440. The KOLs also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

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[115] U.S. Senate Homeland Security & Governmental Affairs Committee, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, (February 12, 2018) https://www.hsdl.org/?abstract&did=808171 ("*Fueling an Epidemic*"), p. 2.

[116] *Id.* p. 1.

[117] *Id.* at 2.

a. The KOLs promised to, and did, make representations regarding Defendants' opioids that were consistent with Defendants' messages themselves;

b. The KOLs distributed promotional and other materials which deceptively claimed that opioids could be safely used for chronic pain and that the benefits of using opioids for chronic pain outweighed the risks; and

c. The KOLs concealed their connections to and sponsorship by Defendants.

441. The scheme devised and implemented by Defendants and members of the Opioid Marketing Enterprise, amounted to a common course of conduct intended to increase the Defendants' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

442. As detailed above, Defendants committed various fraudulent acts which constitute fraud and a scheme to defraud. These intentional omissions of material fact and affirmative representations made by Defendants were false when made which included but was not limited to the acts detailed above and the following acts:

a. Marketing materials about the Defendants' opioids, and their risks and benefits, which Defendants distributed and made available to health care providers and consumers located across the country and in Plaintiffs' communities;

b. Unbranded marketing materials about the use of opioids in treating chronic pain, and their risks and benefits, which Defendants distributed and made available to health care providers and consumers located across the country, including in Plaintiffs' communities;

c. Websites and on-line CMEs about the use of opioids in treating chronic pain, and their risks and benefits, which the Defendants, directly and through their front groups, made available to health care providers and consumers located across the country and in Plaintiffs' communities;

d. Upon information and belief, written representations and telephone calls between Defendants and front groups regarding representations about Defendants' opioids, or the use of opioids for chronic pain generally;

e. Upon information and belief, distributing materials and talking points to sales representatives electronically and by mail and phone;

f. Upon information and belief, written representations and telephone calls between Defendants and KOLs regarding Defendants' opioids, or the use of opioids for chronic pain generally;

g. Upon information and belief, e-mails between the Defendants and the front groups agreeing to or effectuating the implementation of the opioid marketing scheme;

h. Upon information and belief, e-mails between the Defendants and KOLs agreeing to or effectuating the implementation of the opioid marketing scheme; and

i. Receipts of increased profits which represented the wrongful proceeds of the scheme.

443. The multiple acts of corrupt activity which the members of the Opioid Marketing Enterprise committed, or aided or abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of corrupt activity, through which the Defendants, the Front Groups and the KOLs defrauded and intended to defraud Ohio consumers, the State, and other intended victims."

444. The pattern of corrupt activity used by Defendants and the Opioid Marketing Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise, including essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain, with the goal of profiting from increased sales of the Defendants' drugs.

D. Damages

445. Defendants' substantial financial contribution to the Opioid Marketing Enterprise, and the advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.[118]

446. The Defendants' violations of law and their pattern of corrupt activity directly or indirectly caused the Plaintiffs' injuries. The Defendants' pattern of corrupt activity logically, substantially and foreseeably caused an opioid epidemic. The Plaintiffs' injuries, as described below, were not unexpected, unforeseen or independent. Rather, as the Plaintiffs allege, the Defendants knew that the opioids were unsuited to treatment of long-term chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, the Defendants engaged in a scheme of deception that utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products.

447. It was foreseeable and expected that a massive marketing campaign utilized by the Defendants that misrepresented the risks and benefits of prescription opioids would lead to a nationwide opioid epidemic, and a devastating public health crisis in Plaintiffs' communities. The Plaintiffs' injuries were logically, foreseeable, and substantially caused by the opioid epidemic that Defendants created.

448. Defendants' pattern of corrupt activity directly and proximately caused the Plaintiffs injuries because Plaintiffs paid for costs associated with the opioid epidemic, as described above in language expressly incorporated herein by reference. But for Defendants' conduct, the Plaintiffs would not have incurred the costs for health care and addiction treatment, law enforcement, child welfare, and other expenditures required as a result of the opioid epidemic.

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[118] *Fueling an Epidemic*, *supra* note 122 p. 1.

449. The Plaintiffs' injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a. Losses caused by the decrease in funding available for the Plaintiffs' public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

b. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;

d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with Naloxone – an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

e. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

f. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;

g. Costs for providing treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by mother during pregnancy;

h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased drug-addicted population;

i. Costs associated with increased burden on Plaintiffs' judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;

e. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;

f. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiffs' community;

g. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and

h. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

450. The misconduct alleged in this case is ongoing and persistent.

451. The misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

452. The Plaintiffs have incurred expenditures for special programs over and above its ordinary public services.

453. The Plaintiffs seek all legal and equitable relief as allowed by law, including, *inter alia,* actual damages; treble damages; equitable and/or injunctive relief, including corrective statements, information and education, under Ohio Rev. Code § 2923.34(B)(1)-(2), requiring divestiture by, and reasonable restrictions upon, the future activities of the Defendants; forfeiture as deemed proper by the Court; attorney's fees and all costs; expenses of suit; and pre- and post-judgment interest, as the Court deems just and applicable.

Count V
Negligence
(Against All Defendants)
(Brought by the County of Stark Board of Commissioners and the Cities of Canton, Massillon, and Alliance, the Plaintiffs in this Count)

454. The Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

455. Defendants owed The Plaintiffs a duty, including a preexisting duty, to not expose The Plaintiffs to an unreasonable risk of harm.

456. Defendants had a legal duty to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in manufacturing, advertising, marketing, selling and/or distributing opioids.

457. As evidence of addiction and abuse of opioids widened, Defendants were obligated to rein in their supply, prevent diversion, and mitigate the harms from opioid overuse and abuse.

458. Defendants had a duty not to breach the standard of care established under Ohio law and the federal Controlled Substances Act ("CSA") and its implementing regulations to report suspicious prescribing and to maintain systems to detect and report such activity.

459. The degree of care the law requires is commensurate with the risk of harm the conduct creates. Defendants' conduct in marketing, distributing, and selling dangerously addictive drugs requires a high degree of care and places them in a position of great trust and responsibility *vis a vis* the Plaintiffs. Their duty cannot be delegated.

460. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in selling dangerous controlled substances.

461. Defendants breached their duty to the Plaintiffs by, *inter alia*:

a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders; and

g. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

462. Defendants breached their duty to the Plaintiffs by deceptively marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain.

463. The Plaintiffs do not allege that Defendants were negligent for failure to protect from harm. Rather, Defendants engaged in conduct the foreseeable result of which was to cause harm to the Plaintiffs.

464. Defendants have engaged in affirmative acts of creating an illegal, secondary prescription opioid market by failing to exercise adequate control over the marketing, distribution, and sale of their prescription opioids.

465. Defendants were negligent by marketing and selling opioids in a way that created and fostered an illegal, secondary prescription opioid market that resulted in a foreseeable and unreasonable risk of harm to the Plaintiffs.

466. The method by which Defendants created this market was by marketing, distributing, and selling opioids without regard to the likelihood that the opioids would be placed in the hands of criminals, addicts, juveniles, and others not permitted to use or possess prescription opioids.

467. A reasonably prudent opioid manufacturer should have anticipated an injury to the Plaintiffs as a probable result of marketing, distributing, and selling prescription opioids in this manner.

468. It was reasonably foreseeable that Defendants' actions and omissions would result in the harm to the Plaintiffs as described herein.

469. Defendants had control over their conduct in Plaintiffs' communities. Defendants controlled their deceptive advertising and efforts to mislead the public, including their acts and omissions in detailing by their sales representatives, online communications, publications, Continuing Medical Education programs and other speaking events, and other means described in this Complaint. Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Each of the Defendants controlled the systems they developed to prevent diversion, including the criteria and process they used to identify suspicious orders, whether and to what extent they trained their employees to report and halt suspicious orders, and whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

470. Because of the Defendants' deceptive marketing of opioids and each of the Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

471. Defendants also misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious orders.

Defendants voluntarily undertook duties, through their statements to the media, regulators, and the public at large, to take all reasonable precautions to prevent drug diversion.

472. Defendants are in the business of manufacturing, marketing, selling and/or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.

473. Indeed, opioids are akin to medical grade heroin. Defendants' wrongful conduct of deceptively marketing and pushing as many opioids onto the market as possible led directly to the public nuisance and harm to Plaintiffs – exactly as would be expected when medical grade heroin in the form of prescription opioids are deceptively marketed, flood the community, and are diverted into an illegal, secondary market.

474. Reasonably prudent manufacturers of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities, and the significant costs which would be imposed upon the governmental entities associated with those communities. Indeed, it is a violation of R.C. § 4729.35 and O.A.C. §§ 4729-9-12, 4729-9-16, and 4729-9-28 for distributors (including Defendant manufacturers who are also registered as distributors) and a violation of R.C. § 4729.35, 21 U.S.C. § 823, and 21 C.F.R. § 1301.74 for Defendants not to report suspicious orders and exercise due diligence not to ship such orders unless and until the suspicion has been removed. The closed system of opioid distribution, whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

475. Defendants knew or should have known, that their affirmative misconduct in engaging in an aggressive, widespread, and misleading campaign in marketing narcotic drugs

created an unreasonable risk of harm. Defendants' sales data, reports from sales representatives, and internal documents, should have put them on notice that such harm was not only foreseeable, but was actually occurring. Defendants nevertheless chose to deceptively withhold information about the dangers of opioids from Plaintiffs, physicians, patients, and the public.

476. Defendants conduct was negligence *per se* in that Defendants violated federal law, including, but not limited to, 21 U.S.C. §§ 823 and 827(d)(1); 21 C.F.R. §§ 1301.74, 1304.21, 1304.22, and 1304.33(e); and Ohio law, including, but not limited to, R.C. § 2925.02(A); and § 4729.01(F), R.C. §§ 4729.51-4729.53, and O.A.C. §§ 4729-9-12, 4729-9-16, and 4729-9-28. Plaintiffs were parties intended to be protected by such laws and whose injuries said laws were designed to prevent. Defendants' violations of said laws proximately caused injury to Plaintiffs.

477. Defendants also violated federal and Ohio statutes and regulations, including the controlled substances laws, by, *inter alia*:

a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders; and

g. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

478. As a direct and proximate result of Defendants' negligence and/or negligence *per se*, Plaintiffs has suffered and will continue to suffer economic damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections, rehabilitation, and other services.

479. As a direct and proximate result of Defendants' negligence and/or negligence *per se*, Plaintiffs has suffered and will continue to suffer stigma damage, non-physical property damage, and damage to its proprietary interests.

480. As a direct and proximate result of Defendants' negligent, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, there is now a national opioid epidemic that has caused enormous harm and injury to the public, and of which Plaintiffs' communities have been uniquely and particularly impacted as communities at the epicenter of the epidemic.

481. Defendants' misconduct alleged in this case is ongoing and persistent.

482. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

483. The Plaintiffs have incurred expenditures for special programs over and above its ordinary public services.

484. The Plaintiffs have suffered an indivisible injury as a result of the tortious conduct of Defendants.

485. The tortious conduct of each Defendant was a substantial factor in producing harm to the Plaintiffs.

486. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

487. The Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

Count VI
Injury Through Criminal Acts
(R.C. § 2307.60)
(Against All Defendants)
(Brought by the County of Stark Board of Commissioners and the Cities of Canton, Massillon, and Alliance, the Plaintiffs in this Count)

488. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

489. R.C. § 2307.60(A)(1) provides that:

> Anyone injured in person or property by a criminal act has, and may recover full damages in, a civil action unless specifically excepted by law, may recover the costs of maintaining the civil action and attorney's fees if authorized by any provision of the Rules of Civil Procedure or another section of the Revised Code or under the common law of this state, and may recover punitive or exemplary damages if authorized by section 2315.21 or another section of the Revised Code.

490. In the distribution and sale of opioids in Plaintiffs' communities, Defendants violated R.C. § 2925.02(A), which states:

491. "No person shall knowingly do any of the following:

> (1) By force, threat, or deception, administer to another or induce or cause another to use a controlled substance; . . . or
>
> (3) By any means, administer or furnish to another or induce or cause another to use a controlled substance, and thereby cause serious physical harm to the other person, or cause the other person to become drug dependent."

492. Defendants' actions in deceptively marketing opioids, as described throughout this Complaint, knowingly induced or caused members of the Plaintiffs' communities to use a controlled substance by deception, in violation of R.C. § 2925.02(A).

493. Through the Defendants' actions as described in this Complaint, including flooding the market with opioids, deliberately disregarding their obligations to maintain effective controls against diversion, Defendants furnished to residents of Plaintiffs' communities or induced or caused residents of Plaintiffs' Community to use a controlled substance, thereby causing serious physical harm to those persons and causing them to become drug dependent, in violation of R.C. §§ 2925.02(A)(3).

494. The exemption in R.C. § 2925.02 only applies to drug manufacturers and wholesalers when their "conduct is in accordance with Chapters R.C. § 3719., 4715., 4723., 4729., 4730., 4731., and 4741." R.C. § 2925.02(B). Defendants are not in compliance with said Chapters and have thereby forfeited the protection provided by the exception.

495. In the distribution and sale of opioids in Ohio and Plaintiffs' communities, Defendants violated R.C. § 2925.02(A)(2), which makes it a crime to: "Prepare for shipment, ship, transport, deliver, prepare for distribution, or distribute a controlled substance or a controlled substance analog, when the offender knows or has reasonable cause to believe that the controlled substance or a controlled substance analog is intended for sale or resale by the offender or another person."

496. Defendants may claim an exemption to R.C. § 2925.03(A)(2) only if their "conduct is in accordance with Chapters 3719., 4715., 4723., 4729., 4730., 4731., and 4741. of the Revised Code." Defendants are not in compliance with said Chapters and have thereby forfeited the protection provided by the exception.

497. Defendants have engaged in additional criminal acts detailed in the Ohio Corrupt Practices Act Counts above, including acts of criminal wire fraud, mail fraud, telecommunications fraud, unlawful dealing in controlled substances, and violations of the Ohio Corrupt Practices Act.

498. It was foreseeable to Defendants that their misconduct alleged in this Count would lead to addiction, abuse, misuse, and diversion of opioids, both in Plaintiffs' communities and throughout the United States.

499. Plaintiffs' were within the zone of interest protected by these criminal laws.

500. As a direct and proximate result of Defendants' criminal acts as described in this Count, Plaintiffs suffered injury and damages, for which Plaintiffs are entitled to recover pursuant to R.C. § 2307.60(A)(1).

501. Defendants' misconduct alleged in this case is ongoing and persistent.

502. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

503. Plaintiffs have incurred expenditures for special programs over and above its ordinary public services.

504. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

505. Plaintiffs seek all legal relief to which they may be entitled pursuant to R.C. § 2307.60(A)(1), including *inter alia* compensatory damages, punitive and/or exemplary damages, attorney's fees, and the costs and expenses of suit, including pre- and post-judgment interest.

Count VII
Unjust Enrichment
(Against All Defendants)
(Brought by the County of Stark Board of Commissioners and the Cities of Canton, Massillon, and Alliance, the Plaintiffs in this Count)

506. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

507. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and purchase of opioids within Plaintiffs' communities, including from opioids foreseeably and deliberately diverted within and into Plaintiffs' communities.

508. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.

509. Plaintiffs have expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

510. These expenditures include the provision of healthcare services and treatment services to people who use opioids.

511. These expenditures have helped sustain Defendants' businesses.

512. Plaintiffs have conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices.

513. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

514. Plaintiffs have paid for the cost of Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products. Because of their deceptive marketing of prescription opioids, Defendants obtained enrichment they would not otherwise have obtained. Because of their conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and Plaintiffs lack a remedy provided by law.

515. Defendants have unjustly retained benefits to the detriment of Plaintiffs, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

516. Defendants' misconduct alleged in this case is ongoing and persistent.

517. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

518. Plaintiffs have incurred expenditures for special programs over and above Plaintiffs' ordinary public services.

519. Plaintiffs seek an order compelling Defendants to disgorge all unjust enrichment to Plaintiffs; and awarding such other, further, and different relief as this Honorable Court may deem just.

Count VIII
Civil Conspiracy
(Against All Defendants)
(Brought by the County of Stark Board of Commissioners and the City of Canton, the Plaintiffs in this Count)

520. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

521. Defendants engaged in a civil conspiracy in their unlawful marketing of opioids and/or distribution of opioids into Plaintiffs' communities.

522. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful marketing of opioids and/or distribution of opioids into Plaintiffs' communities.

523. Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids.

524. The Marketing Defendants further unlawfully marketed opioids in Plaintiffs' communities in furtherance of that conspiracy.

525. Defendants' conspiracy and acts in furtherance thereof are alleged in detail in this Complaint, including, without limitation, in Plaintiffs' Counts for violations of the Ohio Corrupt Practices Act. Such allegations are specifically incorporated herein.

526. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly caused the injuries alleged herein.

527. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

528. Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue engaging in their unlawful conduct.

529. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

530. Defendants' actions demonstrated both malice and also aggravated and egregious fraud. Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm. Defendants' fraudulent wrongdoing was done with a particularly gross and conscious disregard.

531. Defendants' misconduct alleged in this case is ongoing and persistent.

532. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

533. Plaintiffs have incurred expenditures for special programs over and above Plaintiffs' ordinary public services.

534. Plaintiffs seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre-and post-judgment interest.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

A. A finding that, by the acts alleged herein, Defendants have created a public nuisance;

B. An injunction permanently enjoining Defendants from engaging in the acts and practices that caused the public nuisance;

C. An order directing Defendants to abate the public nuisance,

D. A finding that, by the acts alleged herein, Defendants violated the Ohio Corrupt Practices Act ("OCPA"), R.C. 2923.31, *et seq.*;

E. A finding that, by the acts alleged herein, Defendants violated R.C. 2307.60;

F. An award of three times the Plaintiffs' actual damages under R.C. 2923.31, *et seq.*;

G. Compensatory damages in an amount in excess of $25,000 sufficient to fairly and completely compensate for all damages alleged herein;

H. Punitive damages in excess of $25,000;

I. Disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein;

J. For costs, filing fees, pre and post judgment interest, and attorney's fees; and

K. For all other relief at law or in equity, deemed just by this Court.

Dated: December 19, 2018

Respectfully submitted,

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JURY DEMAND

Plaintiffs request a jury be seated to try all issues of fact and law presented herein.

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